BTL-4000 Series

USER'S MANUAL

v100z2AM16/07/2004EN

Dear Customer,

Thank you for buying our medical equipment of the BTL-4000 Series. We hope that you will be satisfied with our product and that thanks to you it will help many patients.

We are interested in your experience with this equipment and your view on possible improvements. That is why we beg to ask you for filling in the enclosed customer card and sending it back to us. Your comments will be a feedback thanks to which we can manufacture our products as good as possible.

We wish you much success at your work.

Best regards,

BTL Industries Limited
Manufacturer of BTL devices

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1 GENERAL CHARACTERISTICS

BTL-4000 Series is a series of devices designed for physiotherapy. Depending on the required configuration it has one or two generators – for electrotherapy, ultrasound therapy and/or laser therapy. The device can be configured for treating of one or two patients and can run up to four independent therapies. The device can be also further upgraded – see the configuration tables of individual devices at the end of this User's Manual.

The BTL-4000 Series devices have extensive databases of preset diagnoses and programs. If the preset diagnoses and programs do not satisfy your needs you can modify them easily and program and save your own therapies (programs). You can also program sequences of therapies. The user therapies and sequences can be saved in the device's memory under the user program number and/or the user diagnosis name. Thanks to this the equipment can be used not only for common medical practice but also for laboratory work.

The BTL-4000 Series devices detect and check the connected accessories. After each switch-on the device tests its internal circuits and generators. During therapy it checks the status on the output – for example in case of electrotherapy it monitors the quality of application of the electrodes to the patient's body, in case of ultrasound it monitors the contact between the ultrasound head and the patient's skin – and according to this status the device automatically adjusts the output intensity value. If contact is bad, the running therapy is automatically interrupted, data (intensity and time) on the current channel tab start blinking and an acoustic signal is emitted.

The BTL-4000 Series devices divide into the following type groups: BTL-4000 Puls – electrotherapy devices, BTL-4000 Sono –ultrasound therapy devices, BTL-4000 Laser – laser therapy devices, and BTL-4000 Combi, made as combinations of the Puls, Sono and Laser models.

The BTL-4000 Series devices enable to perform combined therapy ultrasound + electrostimulation. Naturally it is possible to choose the ultrasound head polarity (anode / cathode), in combined therapy it is also possible to utilize interference currents.

Recommended therapies for the BTL-4000 Series devices, contraindications, additional information about therapies and references to related literature are in the User's Guides that are supplied together with each device.

Device BTL-4000 Puls and BTL-4000 Combi can be interconnected with the BTL vac vacuum unit, to apply electrotherapy using its suction cup electrodes. If the pulse mode is selected on BTL vac, electrotherapy can be further combined with simple mechanotherapy. The BTL vac device can be controlled by the BTL-4000 Series device – suction in the vacuum electrodes is adjusted according to the intensity of the output current.

Devices BTL-4000 Puls and BTL-4000 Combi with the electro-generator can apply a wide range of currents – galvanic current, diadynamic currents, TENS currents, interference currents, a wide range of pulses, microcurrents, even the high-voltage therapy. For most of the currents the output mode can be selected – constant current or constant voltage (the constant voltage mode is suitable especially for combined therapy and/or stimulation by a point electrode, or if as a result of various circumstances the intensity in the CC mode decreases).

Devices BTL-4000 Sono and BTL-4000 Combi with the ultrasound generator work with the ultrasound heads of a size of 1 cm^2 or 4 cm^2; the frequency of the ultrasound waves can be set to 1 MHz or 3 MHz, which influences the depth of their penetration into the tissue. You can select either continuous or pulse mode of ultrasound waves, set the pulse frequency or the "duty factor".

Devices BTL-4000 Sono and BTL-4000 Combi with the laser generator work with the laser probes, which can generate many types of laser radiation (red, infrared, divergent or convergent beam, etc.). The probe types include probes with green supplementary lighting of the laser beam; you can select the continuous or pulse mode of the laser and set the pulse frequency and the "duty factor".

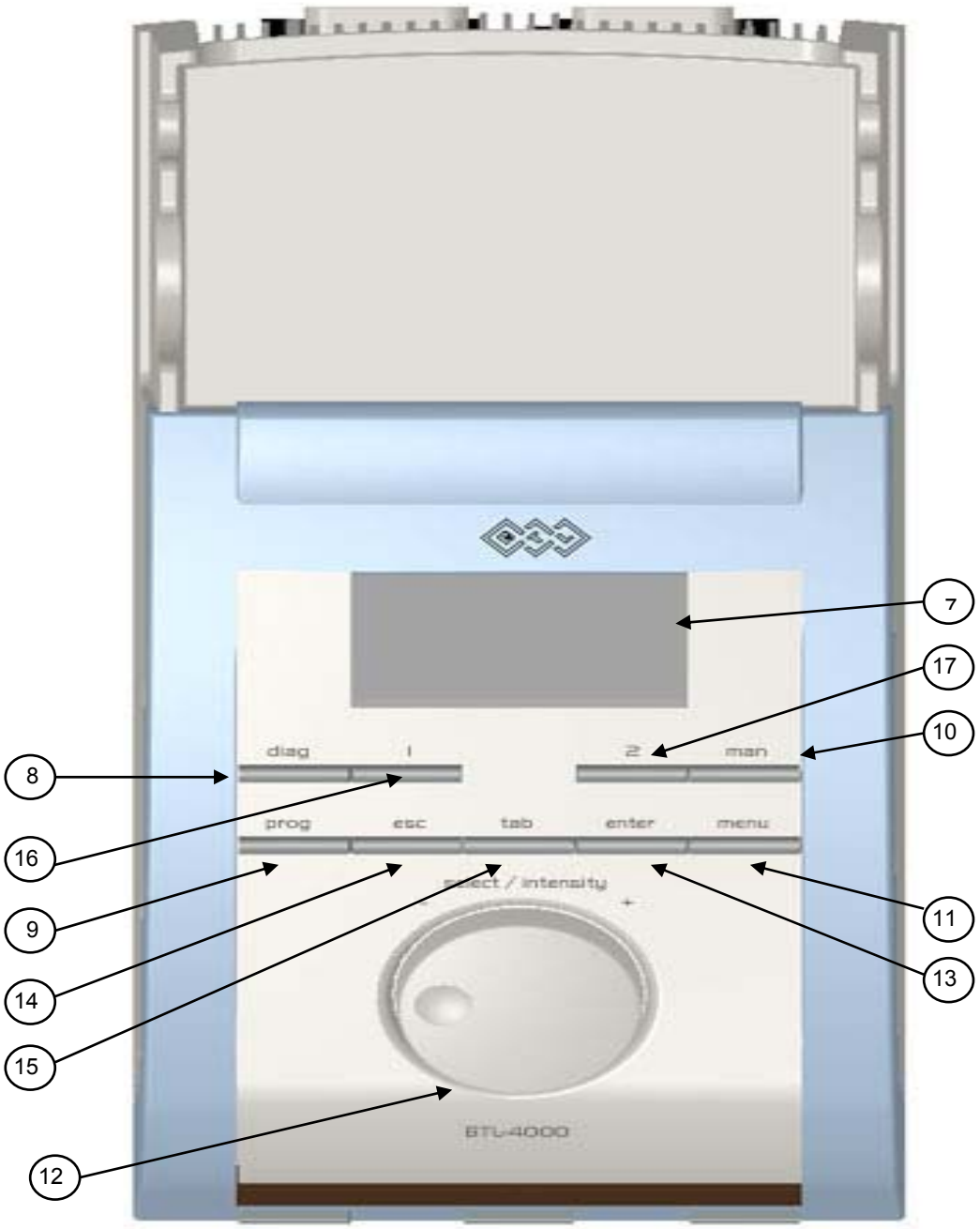
For the latest information about BTL products and for contact to the BTL companies please refer to our website http://www.btlnet.com.

2 INSTRUCTIONS FOR USE

2.1 DESCRIPTION OF THE DEVICE

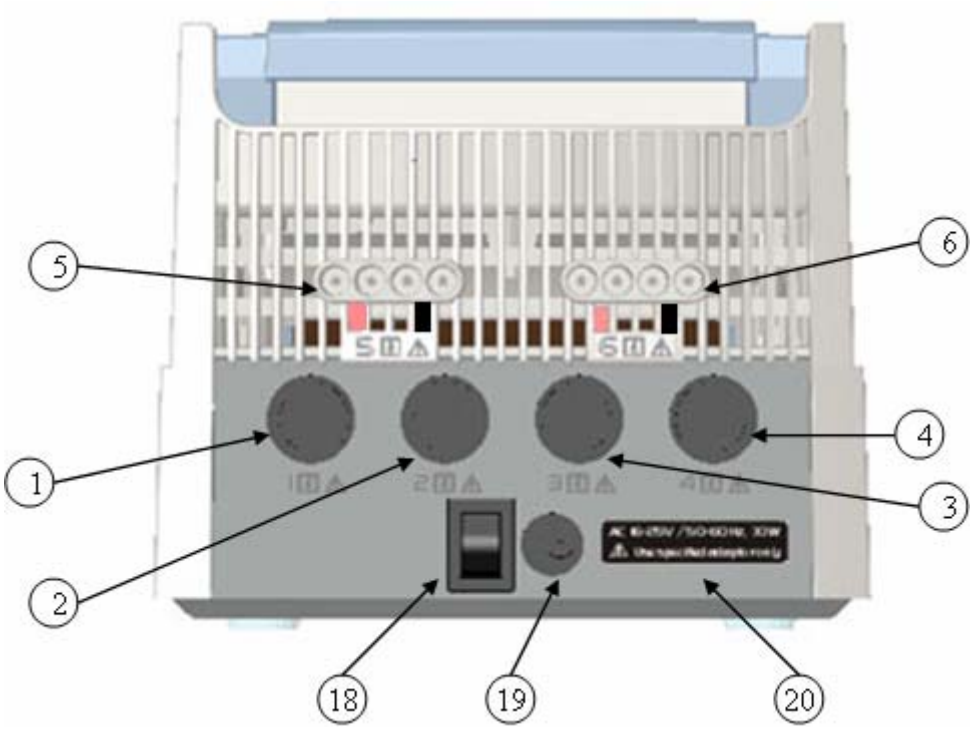
2.1.1 Top Panel

1 - **6** outputs for patient cables on the rear panel of the device, see **2.1.2 Rear Panel**
7 display
8 **diag** button for quick selection of diagnosis
9 **prog** button for quick selection of therapy program
10 **man** button for manual setting of all therapy parameters
11 **menu** button (setting of date, time, language, display contrast, sounds, customizing, etc.)
12 **select/intensity** knob (selection and setting of individual parameters)
13 **enter** button (confirmation of selection or setting)
14 **esc** button (rejection of selection or setting and return to the previous state)
15 **tab** button for switching between the buttons on the display
16 button **1** for switching to the tab of the first generator
17 button **2** for switching to the tab of the second generator


7
17
10
8
16
9
14
15
12
11
13
diag
1
2
man
prog
esc
tab
enter
menu
select / intensity
BTL-4000

2.1.2 Rear Panel

1 - **6** patient outputs – for exact configuration see table **Tab. 2.1**
18 mains switch for switching the device on/off – positions 1 / 0.
19 socket for connection of external power supply adapter BTL-228
20 warning label with parameters of power supply and input of the device



Tab. 2.1 Configuration of Output Connectors

Device Type	output **1**	output **2**	output **3**	output **4**	output **5**	output **6**
BTL-4610 Puls Optimal						E1opti
BTL-4615 Puls Optimal						E1opti
BTL-4621 Puls Optimal						E1opti
BTL-4620 Puls Optimal					E2opti	E1opti
BTL-4625 Puls Optimal					E2opti	E1opti
BTL-4110 Laser Optimal	L1A	L1B	door	acup.		
BTL-4120 Laser Optimal	L1A	L1B	door	L2A		
BTL-4710 Sono Optimal	U1A	U1B	E input	E output		
BTL-4810 S Combi Optimal	U1A	U1B				E1opti
BTL-4815 S Combi Optimal	U1A	U1B				E1opti
BTL-4821 S Combi Optimal	U1A	U1B				E1opti
BTL-4810 L Combi Optimal	L1A	L1B	door			E1opti
BTL-4815 L Combi Optimal	L1A	L1B	door			E1opti
BTL-4821 L Combi Optimal	L1A	L1B	door			E1opti
BTL-4800 SL Combi Optimal	U1A	U1B	door	L1A		
BTL-4610 Puls Professional*				E1		
BTL-4615 Puls Professional*				E1		
BTL-4621 Puls Professional*				E1		
BTL-4620 Puls Professional			E2	E1		
BTL-4625 Puls Professional			E2	E1		
BTL-4640 Puls Professional			E2	E1		
BTL-4110 Laser Professional	L1A	L1B	door	acup.		
BTL-4120 Laser Professional	L1A	L1B	door	L2A		
BTL-4710 Sono Professional	U1A	U1B	E input	E output		
BTL-4810 S Combi Professional	U1A	U1B		E1		
BTL-4815 S Combi Professional	U1A	U1B		E1		
BTL-4821 S Combi Professional	U1A	U1B		E1		
BTL-4810 L Combi Professional	L1A	L1B	door	E1		
BTL-4815 L Combi Professional	L1A	L1B	door	E1		
BTL-4821 L Combi Professional	L1A	L1B	door	E1		
BTL-4800 SL Combi Professional	U1A	U1B	door	L1A		

* can be extended by the HVT module

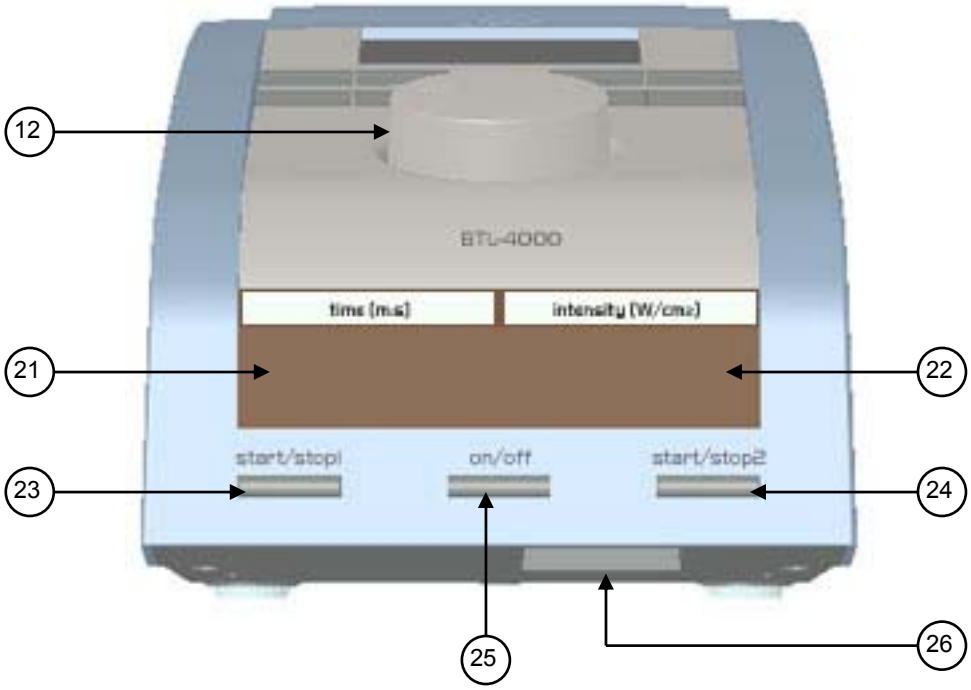
Legend:

E1 connector for connection of electrotherapy accessories (BTL-236-1(2), BTL vac) to the **E1** generator
E2 connector for connection of electrotherapy accessories (BTL-236-1(2), BTL vac) to the **E2** generator
E1opti connector for connection of electrotherapy cables (BTL-226, BTL vac) to the **E1** generator
E2opti connector for connection of electrotherapy cables (BTL-226, BTL vac) to the **E2** generator
L1A connector for connection of laser probe BTL-448, e.g. red, to the **L1** generator
L1B connector for connection of laser probe BTL-448, e.g. infrared, to the **L1** generator
L2A connector for connection of laser probe BTL-448, e.g. red, to the **L2** generator
L2B connector for connection of laser probe BTL-448, e.g. infrared, to the **L2** generator
U1A connector for connection of ultrasound head BTL-237, e.g. 1 cm^2, to the **U1** generator
U1B connector for connection of ultrasound head BTL-237, e.g. 4 cm^2, to the **U1** generator
E input connector for input of external electrotherapy **BTL-46xx, BTL-56xx** on the ultrasound device at combined therapy
E output connector for output of external electrotherapy **BTL-46xx, BTL-56xx** on the ultrasound device at combined therapy
door connector for the open door sensor
acup. **c**onnector for the acupuncture electrode

To see how many patients and to which outputs you can simultaneously connect, press **menu / accessories / connectors - information**.

2.1.3 Front Panel

21 display of the remaining time of therapy for the first channel
22 display of the remaining time of therapy for the second channel
23 **start/stop1** button for starting/stopping of therapy on the first channel
24 **start/stop2** button for starting/stopping of therapy on the second channel
25 **on/off** switch – serves for switching the device on/off
26 service connector under a cover and the type, manufacture and warning labels (placed on the bottom cover of the device)



2.2 ASSEMBLY AND PUTTING INTO OPERATION

Unpack the equipment and place it on a stable horizontal surface proportioned for the equipment's weight, out of reach of sunlight. During the operation the equipment gets warm, therefore it must not be located close to heat-producing devices. Cooling of the equipment is provided by forced air circulation. Cooling vents are located on the rear panel of the equipment and must not be covered. Place the equipment so that the free space behind the rear side is at least 10 cm. Do not put the equipment on a soft surface so as not to obstruct the airflow. Do not put any heat-producing devices on the equipment, neither objects containing water or other liquid. Do not place the equipment close to devices producing strong electromagnetic, electric or magnetic field (diathermy, X-rays, etc.), otherwise the equipment could be undesirably influenced. In case of any questions please contact an authorized service of BTL devices.

The same installation conditions apply for the BTL-228 power supply adapter and must be observed.

We recommend keeping the packing of the equipment for further possible transport.

Plug the device in the mains socket by means of the BTL-228 power supply adapter (see Chapter **6 Technical Parameters.**

Plug the power supply adapter directly in the mains socket; do not use any multi-connection extension cable or adaptor.

Check of correct mains voltage 230 V (115 V)
Before first connection of the external power supply adapter BTL-228 to the mains check if the mains voltage switch on the adapter is in the position corresponding to the local network parameters (i.e. either in the position 230 V or in the position 115 V). For details see **4.1 Power Supply Adapter BTL-228.**
In case of any questions contact the authorized service of BTL devices.

Switching the device on:
Connect the power supply adapter to the device and plug its mains cable in the mains socket, switch the **O**/ **I rocker switch** (**18**) on the rear panel to the **I** position and in the end press the ON/OFF switch (**25**) on the front panel. If the internal functions test passes OK, the display writes the device type and the equipment is ready for operation – see Note.

Connection of accessories
Connect the supplied accessories successively to the **output connectors** (**1**) to (**6**) on the rear panel of the device according to **Tab. 2.1**. The unit automatically detects the accessory, determines its type and displays it in the corresponding tab on the screen. If you happen to connect unsuitable accessory, e.g. a laser probe to the electrotherapy generator, the screen displays a warning and information where the accessory shall be connected.

Recharging of accumulator
If the device contains internal accumulator (the Professional variant), it is sold in half-charged status. That is why we recommend formatting of the accumulator after purchase of the device: connect the device to the mains via the external adapter for at least 48 hours without interruption, the **mains rocker switch** (**18) in position 1**. The device will be recharged and the accumulator will be properly formatted. The properly formatted accumulator enables longer operation of the device without . For details see **4.2 Accumulator**.

Restart of the device - reset
If for a reason (electromagnetic interference, etc.) the device stops responding to the user's commands and the message "please wait..." with small moving squares is not displayed, the device can be put into the initial state by simultaneous pressing of the **prog (9)** and **menu (11)** buttons. After this the device immediately gets into the initial status as well as after switch-on of power supply.
The **mains switch (18)** on the rear panel has the same effect – the whole device switches off; however, we recommend using the above described combination of keys **prog + menu** which is more friendly to the electronics of the device.

Note:
After the switch-on the equipment tests its internal functions (for approx. 5 – 10 seconds) and in case of any discrepancy it alerts to it and, if needed, locks itself in the secure state. In such case it is necessary to contact the authorized service of BTL devices.

2.3 BASIC OPERATING OF THE DEVICE

The display contains several graphic elements. Some of them are only for information, some can be activated. The basic elements are the following:

- buttons (it is possible to activate them by the **tab** button **(15)** and to change their values.) The activated buttons are displayed inversely.
- information texts
- channel tabs (switching between the tabs, selection)

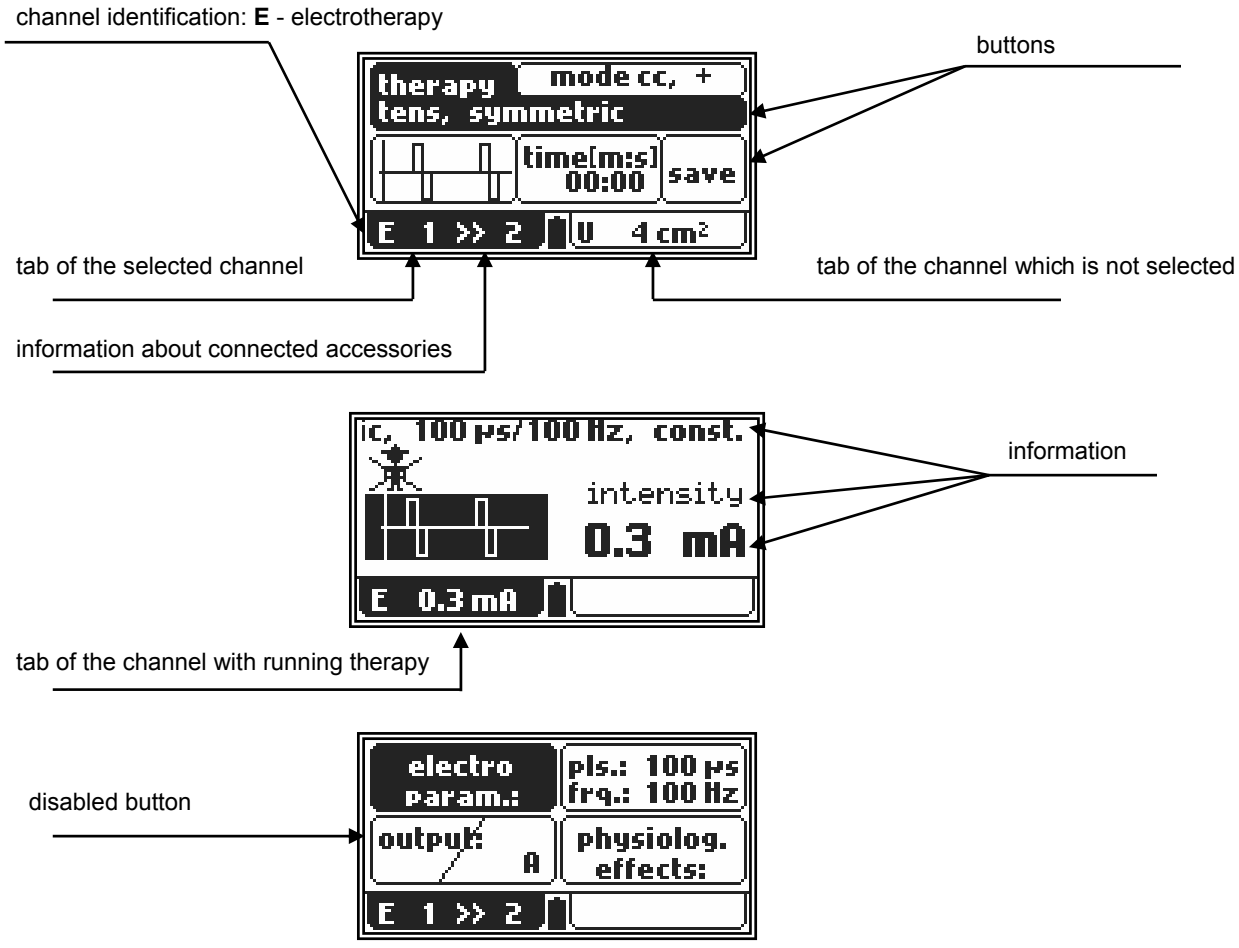
The buttons can be enabled or disabled. The disabled buttons are crossed out.

All the displayed enabled buttons can be successively activated by pressing the **tab** button **(15)**. By repeated pressing of this key further buttons on the screen are successively activated.

If the button contains one numeric value, this value can be directly changed by the **select/intensity** knob **(12)**. If the button contains more numeric values or an item selected from a list, pressing of the **enter** button **(13)** opens the detailed subscreen of the button. To leave the subcscreen press **esc (14)** – all data you have changed will remain changed.

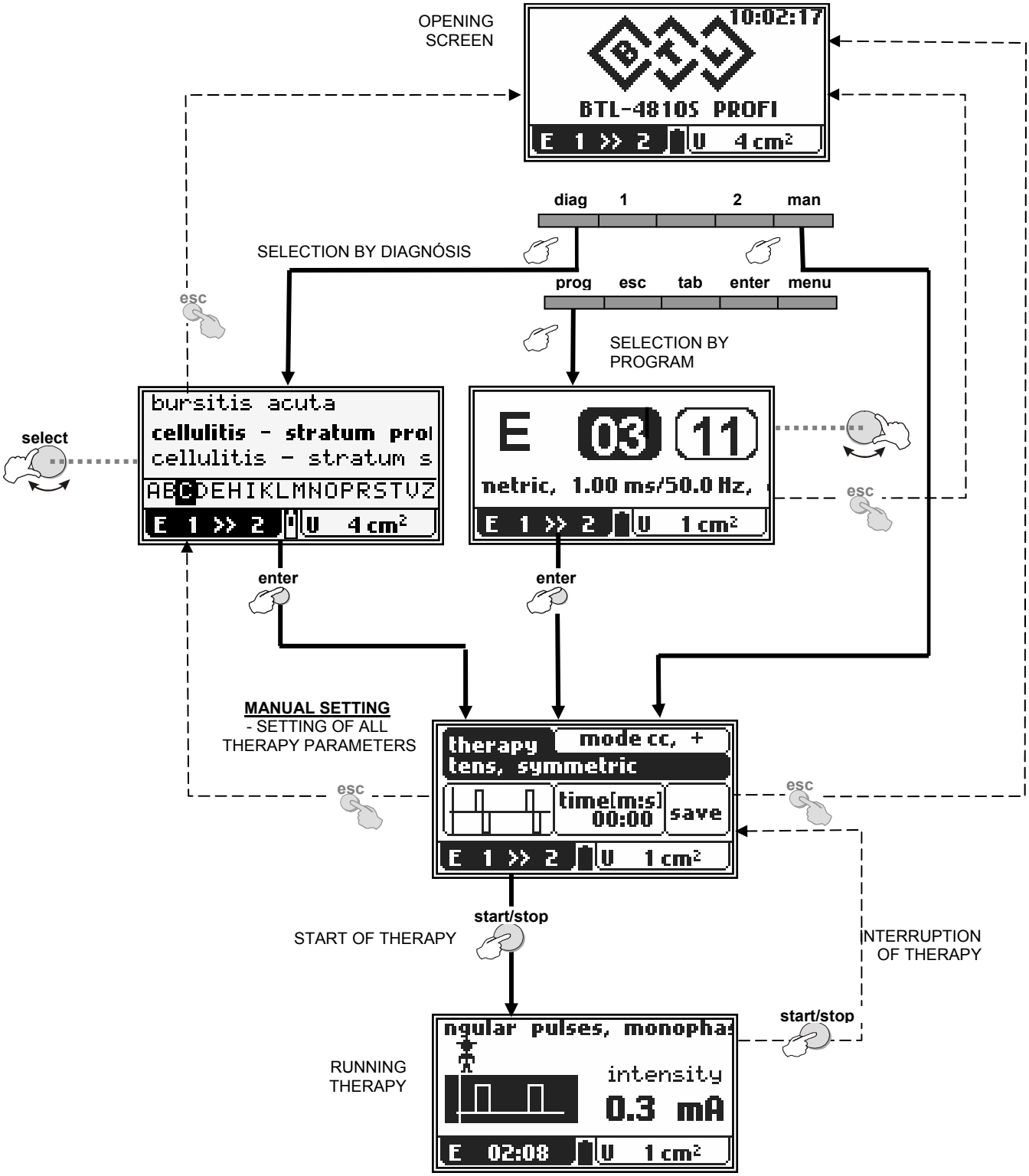
Information texts
The text is displayed directly on the display, in a menu or in a button. If a text is too long and does not fit on the display in full, after a while it starts scrolling automatically.

Selected channel
Although most of the devices of the BTL-4000 Series can run more therapies at a time, only one channel can be controlled at the particular moment, That channel is called the "selected channel". The tab of the "selected channel" in the bottom part of the screen is coloured dark. All information on the screen and all controls relate to this channel. The most important information about the therapies on the other channels remains visible on their tabs.



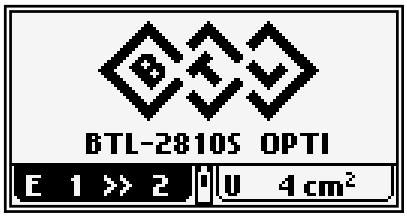
2.4 THERAPY (PRINCIPLE OF SETTING)

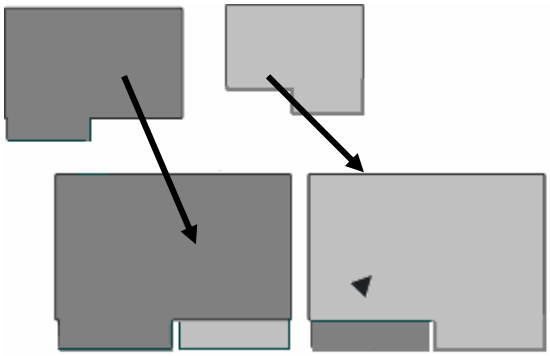
2.4.1 Therapy Setting Flowchart



2.4.2 Opening Screen and Selection of Channels, Tabs, Accessories

Besides the initial information, this screen contains channel tabs with description of the connected accessories. The number of channels – tabs depends on the required configuration of the device. To display all information of the channel press button**1 (16)** or **2 (17)** under the tab. The information set on the "invisible channels" remain preserved. The following scheme shows that almost the entire screen is available for the "selected channel".





Buttons **1(16)** and **2(17)** located directly under the tabs serve for switching between the tabs.

On the channels where more accessories can be connected to one generator (ultrasound generator and two ultrasound heads, laser generator and laser probes), repeated pressing of the tab's button serves for switching between these accessories.

The tab of the channel which is selected (i.e. its information is just on the display) is black.

Examples of information on the tabs:

tab of the selected E channel to which no accessory is connected

tab of the E channel which is not selected, with connected accessory BTL-236-2

tab of the U generator which is not selected, with connected ultrasound head; pressing of buttons **1 (16)** and **2 (17)** under the tab serves for switching between the connected heads – 1 cm^2/4 cm^2

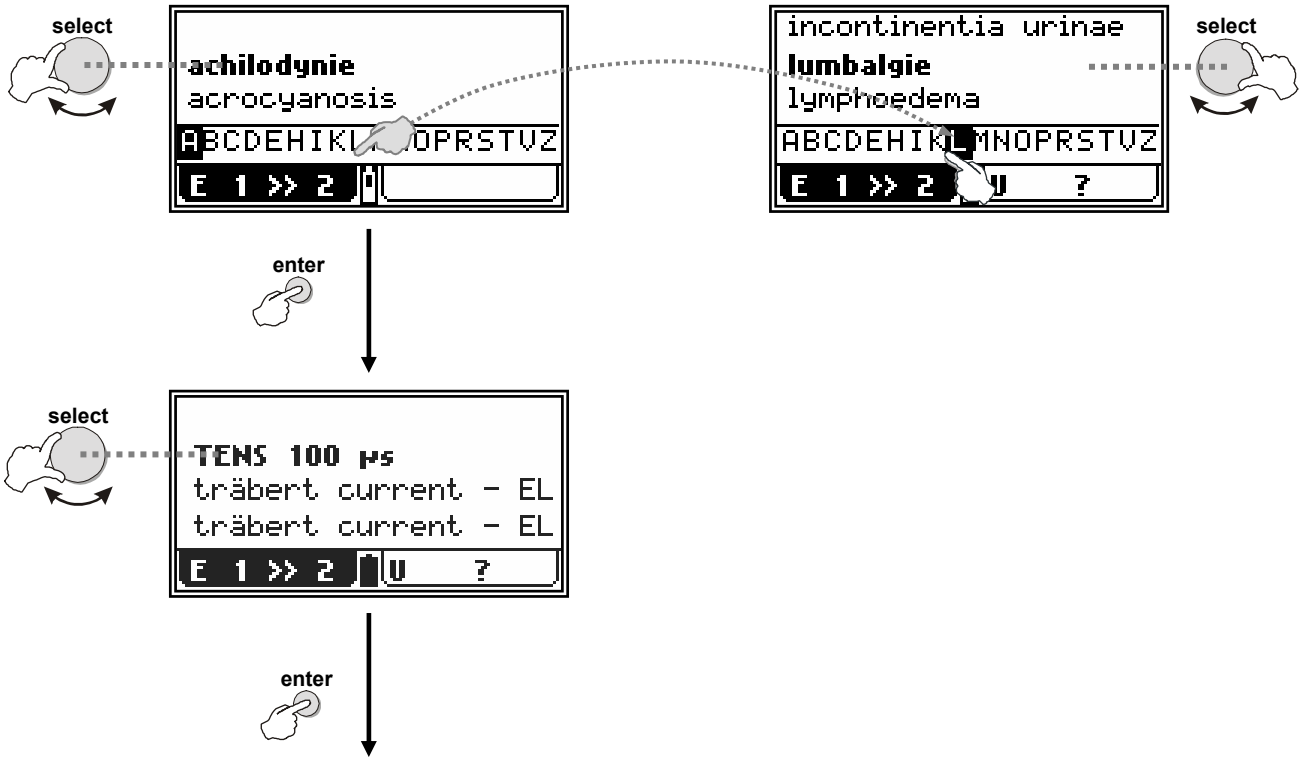
tab of the selected L generator with connected laser probe; pressing of buttons **1 (16)** and **2 (17)** under the tab serves for switching between the connected probes– 685nm/830nm (red/infrared)

tab of the selected E2 channel with unsuitable connected accessory, which this generator cannot work with

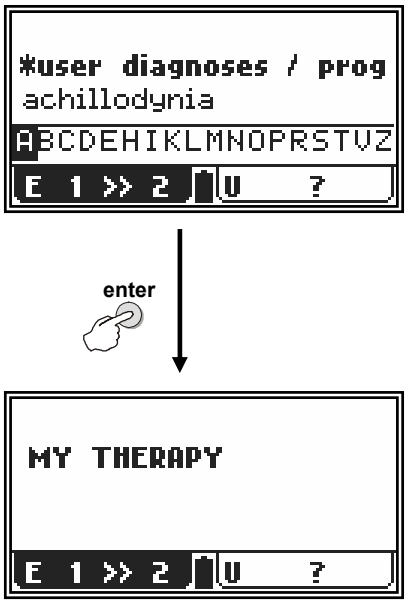
2.4.3 Setting of Therapy Parameters by Selection of Diagnosis – "diag" button

To view the list of diagnoses press the **diag** button (**8**). Each tab – channel – is assigned the list of diagnoses which can be performed on this tab. For example, on the U generator tab you can find all diagnoses which can be performed with the ultrasound heads. On the E generator tab you can find all diagnoses which can be treated by electrotherapy;

in addition the list can contain e.g. diagnoses for high-voltage and/or combined therapy, depending on the configuration of the device.
For moving in the list of diagnoses use the **select** knob **(12)**, the currently selected diagnosis is displayed in bold.
For fast finding of a diagnose select its initial letter by the **tab** button **(15)**.
After finding of the required diagnosis select it by pressing the **enter** button (**13**). If the diagnosis is assigned more therapies – e.g. the treatment can be done by several various types of current – the list of therapies appears after selection of the diagnosis. Select the required therapy by the **select** knob **(12)** and press **enter** (**13**) again.



The user therapies which you create yourselves are in the ***user diagnoses / programs** directory. Their list appears after pressing the **enter** button **(13)**.



2.4.4 Setting of Therapy Parameters by Selection of Program – "prog" button

After pressing the **prog** button (**9**) a screen opens where you can enter the number of the required therapy program. The program number contains the prefix, i.e. the letter corresponding to the therapy principle: **E** – electrotherapy; **U** – ultrasound; **L** – laser therapy.

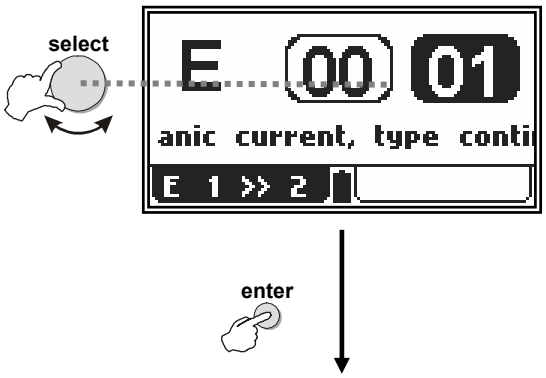
Combined therapies **E+U** are sorted among the **E** programs and are on the E1 electrotherapy tab – in the following pictures on the E1 channel. They are on positions **E-35xx** to **E-39xx**.

Your user diagnoses (except sequences) are stored under the program numbers **E-80xx** to **E-89xx** for electrotherapy, **U-80xx** to **U-89xx** for ultrasound therapy and **L-80xx** to **L-89xx** for laser therapy.

Your user sequences are stored under the program numbers **E-95xx** to **E-99xx** for electrotherapy, **U-95xx** to **U-99xx** for ultrasound therapy and **L-95xx** to **L-99xx** for laser therapy.

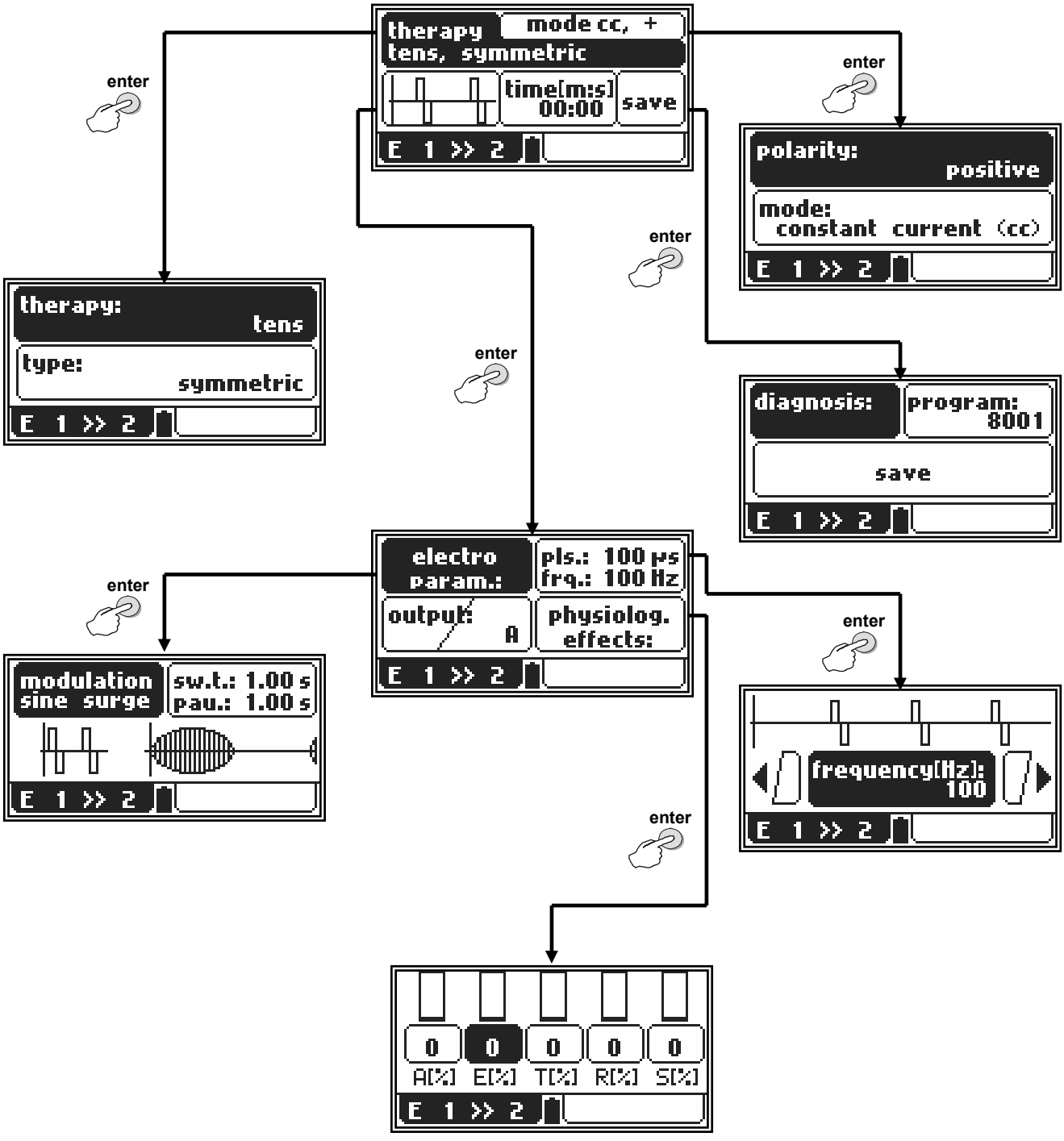
The recommended programs assigned to recommended diagnoses are in the User's Guide.

For faster setting, the program numbers are arranged into pairs. For change of the number use the **select** knob **(12)**, for switching between the pairs of digits use the **tab** key **(15)**.



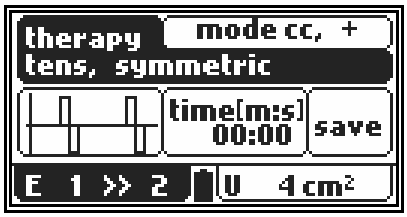
2.4.5 User Setting of Therapy Parameters –"man" button

The therapy parameters screen for user (manual) setting appears after pressing the **man** button **(10)**. All therapy parameters can be set and saved as a user program or diagnosis.
It Is obvious that the therapy parameters screens of individual currents of electrotherapy, ultrasound therapy and laser therapy differ in dependence on the options which can be set in the particular moment. For more details see the respective User's Guide.
To open the required menu or setting dialog select the respective button by the **tab** key **(15)** and then press **enter (13)**. Most dialogs are accompanied with illustration pictures and symbols. See the scheme of possibilities of individual settings in this mode.


therapy
mode cc, +
tens, symmetric
time[m:s]
00:00
save
E 1 >> 2
enter
therapy:
tens
type:
symmetric
E 1 >> 2
enter
polarity:
positive
mode:
constant current (cc)
E 1 >> 2
enter
diagnosis:
program:
8001
save
E 1 >> 2
enter
electro
param.:
pls.: 100 µs
frq.: 100 Hz
output:
A
physiolog.
effects:
E 1 >> 2
enter
modulation
sine surge
sw.t.: 1.00 s
pau.: 1.00 s
E 1 >> 2
enter
frequency[Hz]:
100
E 1 >> 2
enter
0 0 0 0 0
A[%] E[%] T[%] R[%] S[%]
E 1 >> 2

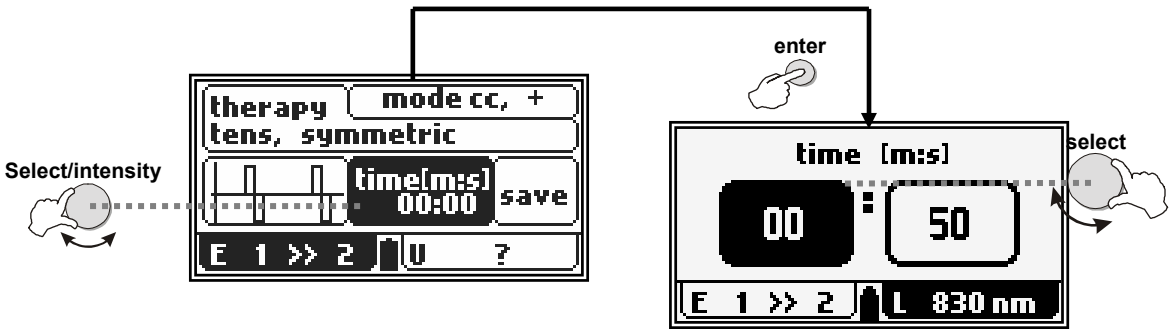
2.4.5.1 Therapy Parameters Screen

This screen opens after selection of therapy after pressing the **diag (8)**, **prog (9)** or **man (10)** button, see. **2.3 Therapy Setting Flowchart.** Before the start of therapy you can change all parameters.



2.4.5.2 Setting of Therapy Time

The time of therapy can be set only on the therapy parameters screen, either by activation of the **time** button and pressing of the **enter** button **(13)** after which the time setting dialog opens, or by fast selection using the **select / intensity** knob (**12**).



By pressing the **start / stop1** (**23**) or **start / stop2 (24)** knob you can start or interrupt therapy – see **2.5.1 Start, Interruption and End of Therapy**.

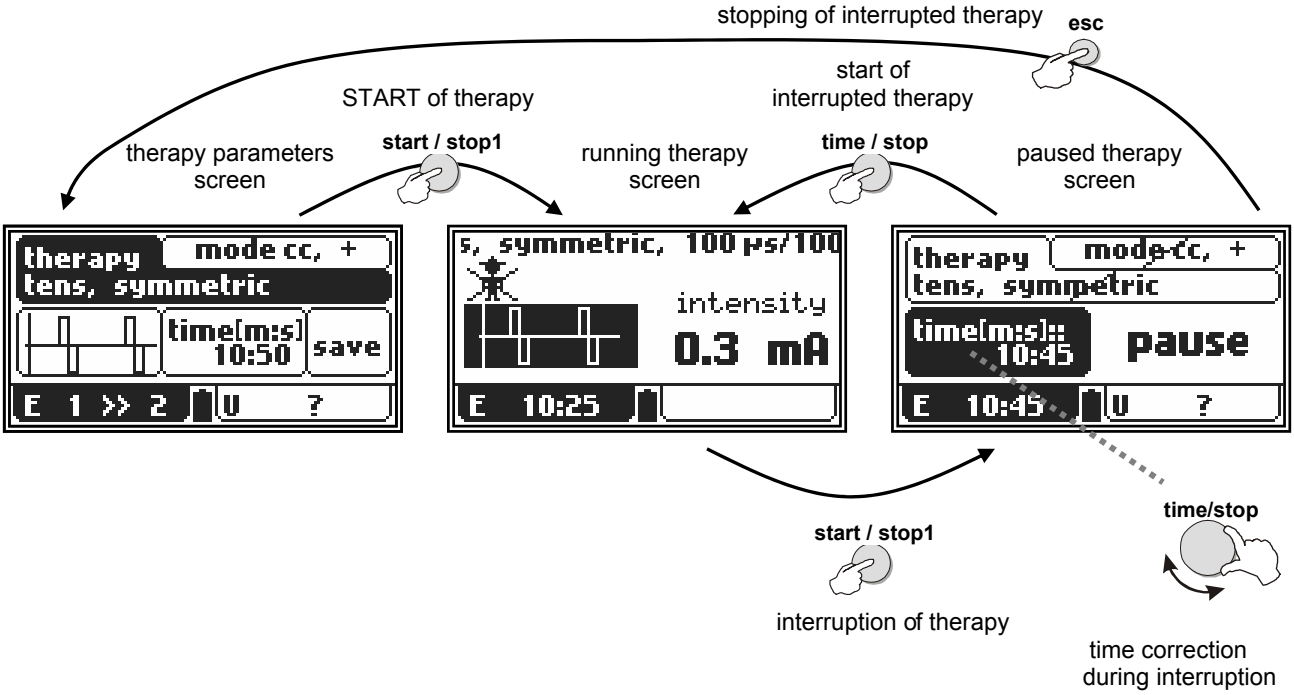
2.4.5.3 Setting of Intensity of Therapy

Intensity (power) of ultrasound and laser therapy can be set only on the therapy parameters screen when the therapy is not running.
In electrotherapy, where intensity is set during therapy, it can be set only by the **select/intensity** knob (**12**).

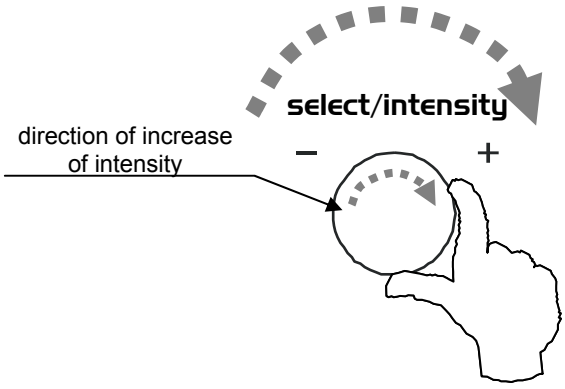
2.5 COURSE OF THERAPY

2.5.1 Start, Interruption and End of Therapy

To start therapy (time of therapy) on the first channel (tab) press the **start / stop1** knob (**23**), to start therapy on the second channel press the **start / stop2** knob **(24)**. Therapy can be started only if the display of the selected channel is displaying the therapy parameters screen.

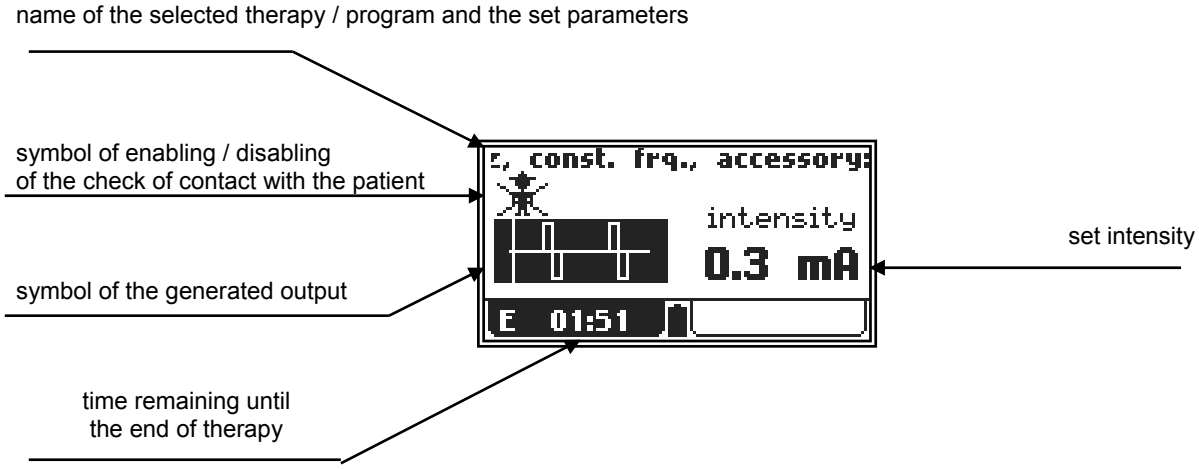


To restart the interrupted – paused – therapy press the **start / stop1** (or **start / stop2**) button, to stop it press the **esc** button (**14**).
During the pause – interrupted therapy – it is possible to modify the time setting by turning of the **select / intensity** knob (**12**) (in laser therapy and all types of sequences it is impossible).



Laser therapy can be also started/interrupted by pressing the **start / stop** button located on the laser probe.

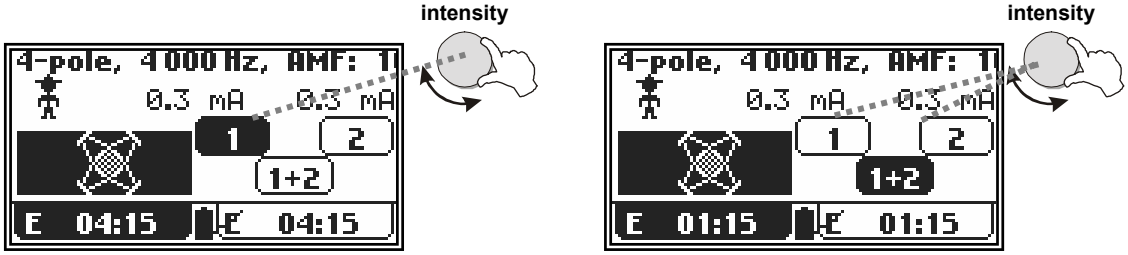
2.5.2 Running Therapy Screen


name of the selected therapy / program and the set parameters
symbol of enabling / disabling
of the check of contact with the patient
symbol of the generated output
time remaining until
the end of therapy
set intensity
intensity
0.3 mA
E 01:51

2.5.3 Electrotherapy – Setting during Therapy

2.5.3.1 Setting the Intensity in 4-Electrode Therapies

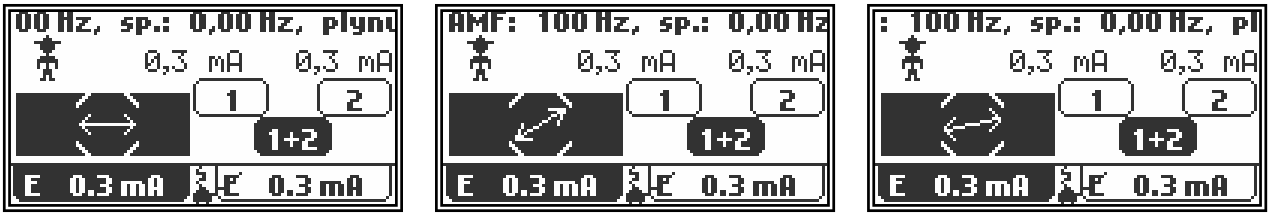
In therapies applied by four electrodes you can set different intensity values between individual pairs of electrodes. For example, in case of 4-pole interference the output intensity is set by the **select/intensity** knob (**12**) either common for both channels (the **1+2** button is active) or separately for one of the channels – the **1** or **2** screen button is active. For switching among the buttons use the **tab** key **(13)**.



If the zero intensity is set on a channel, the therapy is stopped.

2.5.3.2 Manual Turning of Vector in Dipole Interference

In manually-controlled dipole interference, the dipole angle in the intersection of the electrodes is set during therapy by the **enter** knob (**13**) for turning to the right, and by the **esc** knob **(14)** for turning to the left. The position of the dipole is symbolized on the screen above the time value.



When you are rotating the dipole, the device automatically switches to the diagnostic – "measuring" mode (Spectrum = 0 Hz) and after setting after approximately 1 - 2 seconds it gradually returns to the therapy mode – (the Spectrum value corresponds to the set value).

2.5.4 Accessories –Signalling of Operation

Accessories BTL-236 (for electrotherapy) and BTL-237 (ultrasound heads) feature blue pilot lights that signal their operating status:

BTL-236-1: patient cable with two electrodes – blue and yellow pilot light:
- **blinks slow** – accessories ready for therapy – therapy settings screen displayed
- **shines permanently** – the device is generating, dangerous voltage may be on the electrodes

BTL-236-2: patient cable with four electrodes – blue and yellow pilot light:
- **blinks slow** – accessories ready for therapy – therapy settings screen displayed; always the pilot light at the selected pair of electrodes A or B is blinking
- **blinks in the rhythm of the generated currents or shines permanently** – the device is generating, dangerous voltage may be on the pair of electrodes A or B at which the pilot light is shining

BTL-237: ultrasound head 1 cm^2 or 4 cm^2 – blue pilot on the head:
- **blinks slow** – accessories ready for therapy – therapy settings screen displayed
- **shines permanently** – the device is generating
- **blinks fast** – the head does not have contact with the patient during generating, the therapy is automatically interrupted and the device waits for reestablishment of the contact

BTL-448: laser probes 635 nm and 830 nm – green pilot light and focusing beam:
- **blinks in the rhythm of the generated laser or shines** – the device is generating laser radiation, during generation the device indicates occurrence of laser radiation by acoustic signal

BTL vac: vacuum unit for electrotherapy – see the **BTL vac** User's Manual

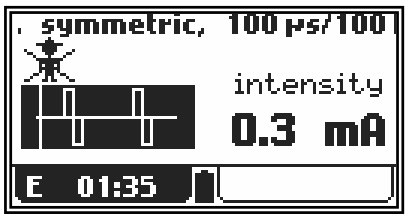
For detailed information please refer to the leaflet which is enclosed to each accessory supplied.

Note:
The tab always displays only a text symbol (description) with no picture.

2.5.5 Indication of Operation – Energy on Output

2.5.5.1 Electrotherapy

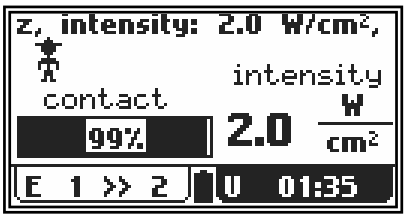
Possible occurrence of electric voltage on the output is indicated:
- on the screen – by the value of intensity of the output current
- on the screen – by an animated icon of running current
- on the channel tab – by the value of intensity or running time
- on the electrotherapy accessory BTL-236 – by the blue and yellow pilot light – for details see Chapter **2.5.4 Accessories –Signalling of Operation**



Disconnection of electric circuit – e.g. in case of bad contact between the electrode and the patient's body – is indicated by blinking of the information about intensity and time on the respective electro-generator tab. This status may be also indicated by a sound signal.
The function of monitoring of contact with the patient may be disabled in the menu of the device.
Enabling/disabling of this function is indicated by the figure symbol (crossed-out if disabled).

Note:
Some types of the generated currents do not allow monitoring of the contact with the patient. In such cases the crossed-out figure is displayed, regardless of the user setting of detection.

2.5.5.2 Ultrasound Therapy

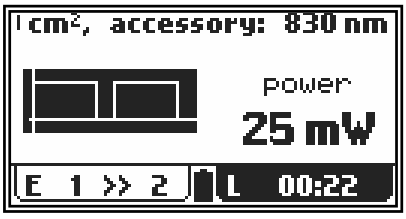


The possibility of generation of ultrasound field by the BTL-237 head is indicated:

- on the screen – by the intensity value
- on the screen – by the contact value (bar-graph)
- on the channel tab – by the running time value
- on ultrasound accessory BTL-237 – by the blue pilot light – for details see Chapter **2.5.4 Accessories –Signalling of Operation**

Bad contact between the head and the patient's body is indicated by fast blinking of the blue pilot lights on the head and blinking of information about intensity and time on the corresponding ultrasound generator tab.
This function is indicated by a figure symbol on the screen.

2.5.5.3 Laser Therapy



The possibility of generation of laser radiation by the BTL-448 probe is indicated:

- on the screen – by the value of power
- by an acoustic signal (which cannot be disabled, as required by the applicable standard)
- by the green indication pilot light on the laser probe
- by the green or red focusing beam
- by the signal icon on the screen
- by the running time value on the channel tab

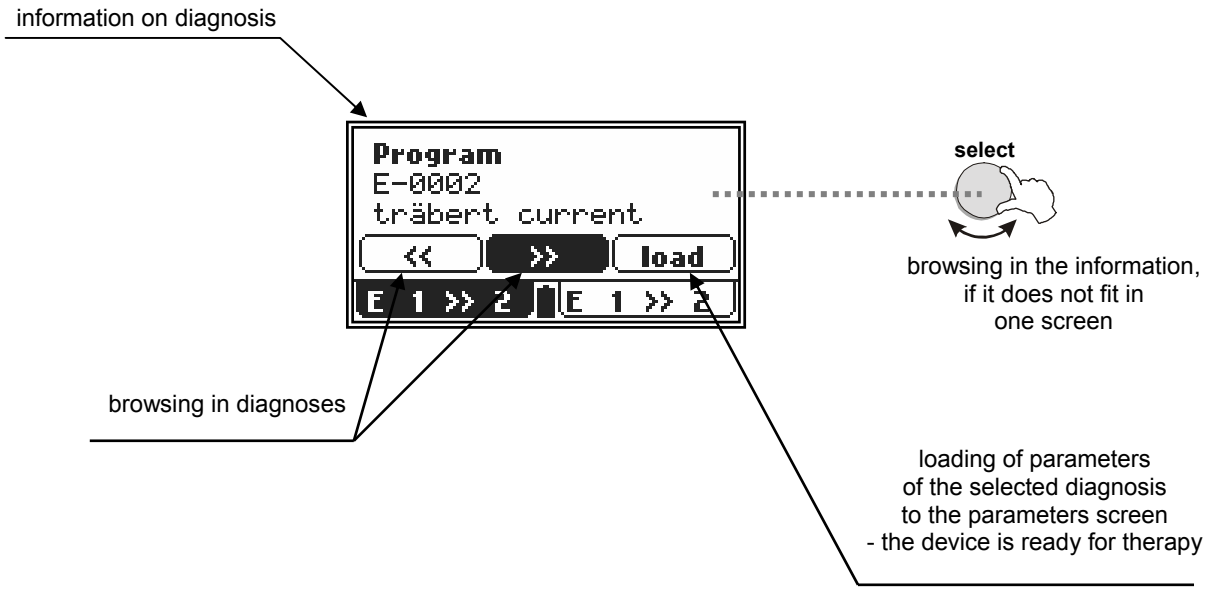
2.6 THERAPY PARAMETERS

Parameters in individual therapies vary. For each therapy only those parameters are displayed which describe the therapy and which can be set in the manual mode after pressing the **man** button **(10)**. For detailed description of parameters of individual therapies refer to the respective **User's Guide**.

2.7 ENCYCLOPAEDIA

The encyclopaedia provides information about possible therapies. The hard copy (paper or CD) is always supplied together with the equipment, its electronic version in the device is available from the menu: **menu / encyclopaedia.**

After opening of the encyclopaedia you get to its contents – the list of diagnoses. For browsing in the list use the **select/intensity** knob (**12**). After selection of the required diagnosis press the **enter** button (**13**) to get the specific information about the diagnosis:


information on diagnosis
Program
E-0002
träbert current
<<
>>
load
E 1 >> 2
E 1 >> 2
select
browsing in the information, if it does not fit in one screen
browsing in diagnoses
loading of parameters of the selected diagnosis to the parameters screen - the device is ready for therapy

2.8 THERAPY SAVING

After pressing the **save** button on the screen, the user can save the particular therapy setting under a name of diagnosis and number of program.

Therapy can be saved always after setting of the therapy parameters – i.e. from the **therapy parameters screen**. The following information is saved with each therapy:

electrotherapy:
- all parameters of currents (e.g. pulse length, pause length, modulation, etc.)
- therapy time
- polarity
- output mode (constant current / constant voltage)

ultrasound therapy:
- all therapy parameters (e.g. ultrasound frequency, duty factor, pulse frequency, etc.)
- therapy time
- intensity

combined therapy electro + ultrasound:
- all parameters of electrotherapy (e.g. pulse length, pause length, modulation, etc.)
- all parameters of ultrasound therapy (e.g. ultrasound frequency, duty factor, pulse frequency, etc.)
- therapy time
- electro output polarity
- electro output mode (constant current / constant voltage)
- ultrasound intensity

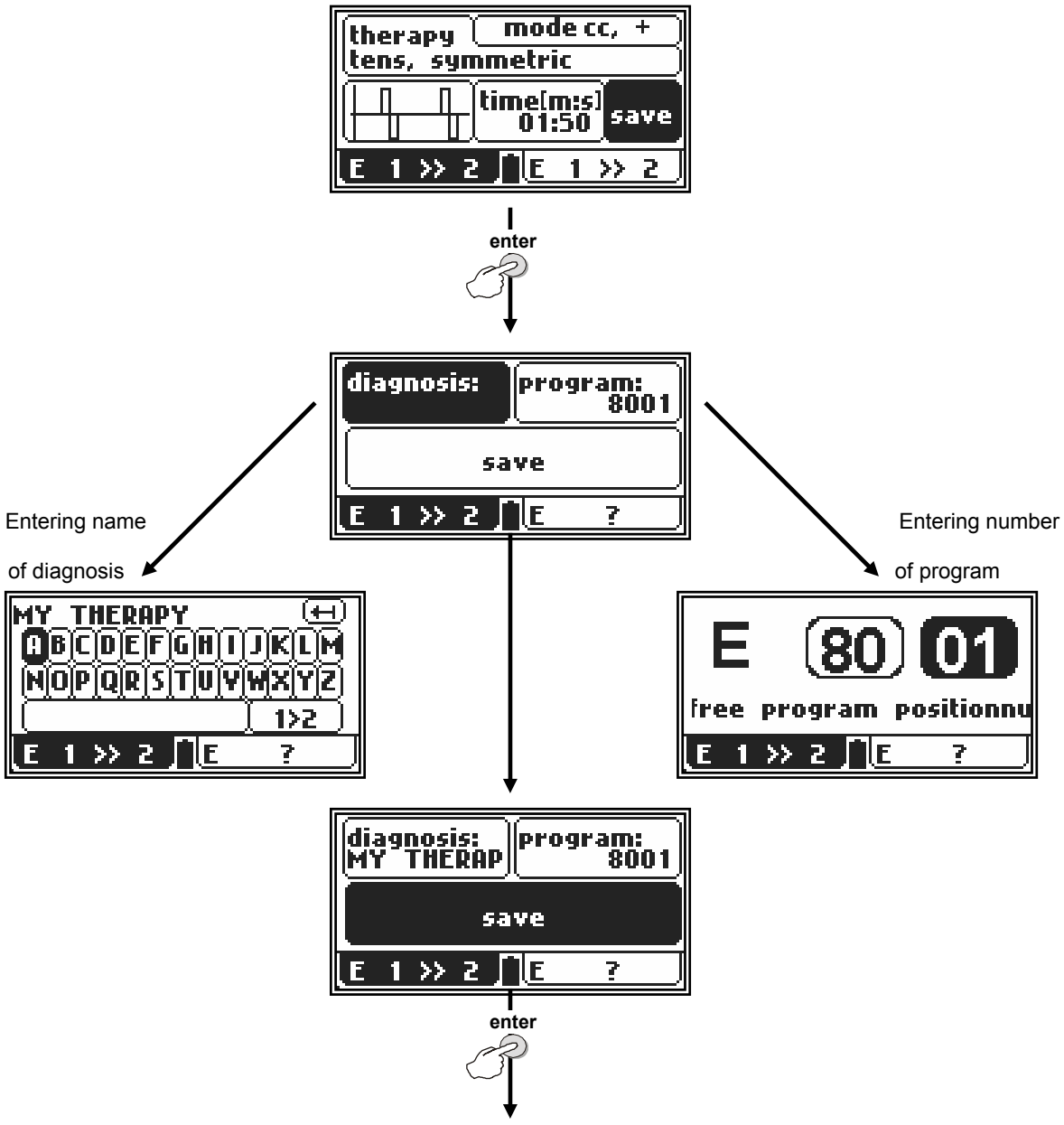
laser therapy:
- all therapy parameters (frequency, course of signal...)
- irradiated area
- dose

When saving therapy, enter the following:

- name of diagnosis (therapy) – will be displayed in the list of diagnoses under the **diag** button (**8**)
- number of program – will be displayed in the list of diagnoses under the **prog** button (**9**)

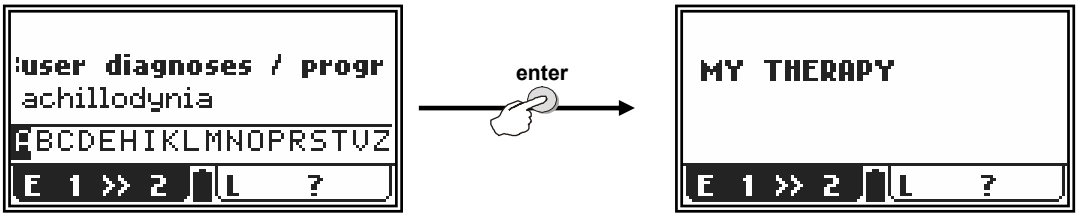
The number of the saved program falls within the interval from 8000 to 8999. The device suggests the lowest available number and adds the letter of the corresponding generator. So the resulting number is for example: E-8001 for electrotherapy or combined therapy, U-8526 for ultrasound therapy and L-8002 for laser therapy.

Setting of therapy parameters and saving of therapy

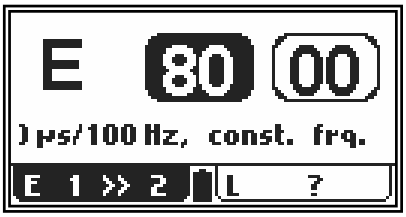


The saved therapy can be found in the following lists on the corresponding channel:

List of diagnoses



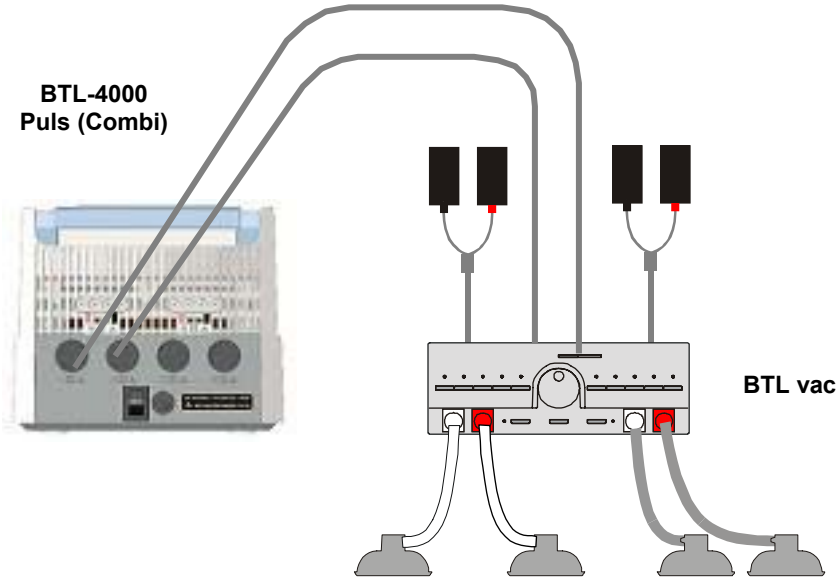
List of programs



2.9 INTERCONNECTION OF DEVICES

2.9.1 Interconnection of BTL-4000 Puls (Combi) and BTL vac

Interconnection of electrotherapy device **BTL-4000 Puls** (or the electrotherapy part of **BTL-4000 Combi**) with the vacuum unit **BTL vac** provides many benefits. Performing electrotherapy by means of the electrodes of the **BTL vac** vacuum unit upgrades electrotherapy by massage programs and provides optimum contact of electrodes with the patient's body.
The outputs of one or two channels of the electrotherapy device are interconnected with the vacuum unit to which vacuum as well as classic electrodes are connected. To switch between them press **vacuum 1** or **vacuum 2** on the front panel of **BTL vac**. If the vacuum unit is off the classic electrodes can be left on it because the output of **BTL vac** in the OFF status is switched to the classic electrodes.



(the pictures are only an illustration, for real interconnection follow **Tab. 2.1 Configuration of Output Connectors**)

For interconnection use the interface cables leading from BTL-4000 Puls outputs E1, E2 (or E1opti, E2opti) and connected to BTL vac inputs **IN1** and **IN2**. For more information see the User's Guide of **BTL vac**.

2.9.2 Interconnection of BTL-4000 Puls and BTL-4000 Sono

If you want to perform combined therapy with these devices, you have to interconnect them mutually – e.g. according to the following table.

Electrotherapy BTL-46xx Puls or BTL-56xx Puls		**Ultrasound BTL-4710 Sono or BTL-5710 Sono**	
Connector	**Connected accessories**	**Connector**	**Connected accessories**
E1	interface cable to ultrasound	U1A	ultrasound head 1 cm^2
E2*	electrodes E2*	U1B	ultrasound head 4 cm^2
		E input	interface cable to electrotherapy
	* if installed	E output	electrodes E1

Setting of polarity between the ultrasound head and the electrode
After interconnection with the electrotherapy device, the ultrasound head becomes the anode (+). The other pole is cathode (-) which is the electrode with black banana plug. If you require that the ultrasound head is the cathode (-) at the combined therapy, set the "negative polarity" in the therapy parameters of the electrotherapy.

ATTENTION

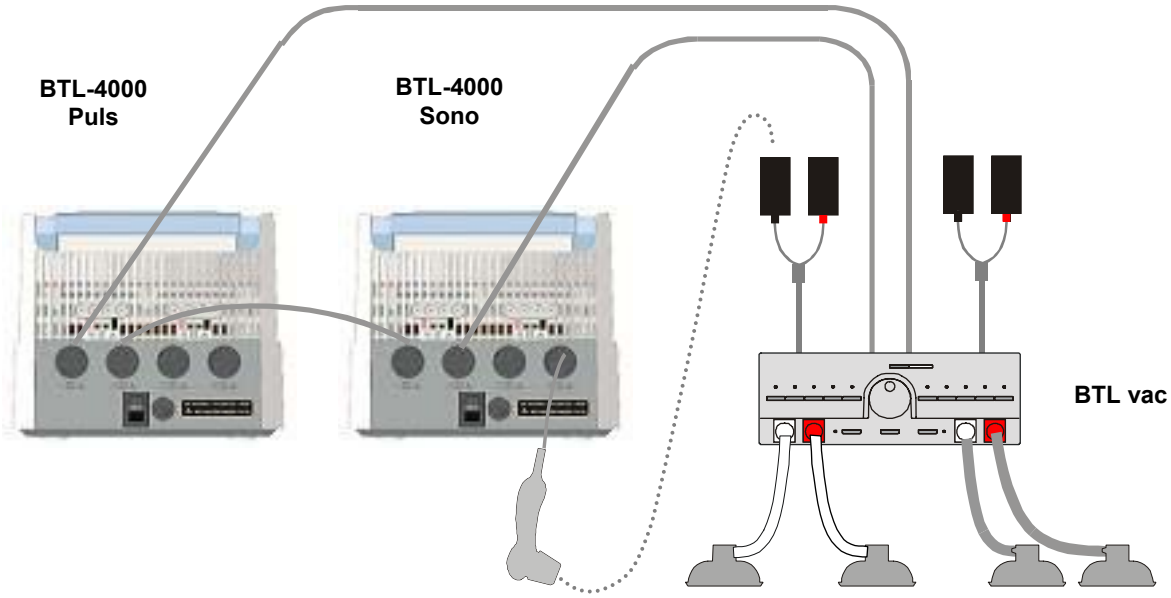
In the case of accesories „**1>>2**“ is connected to the electrotherapy device the ultrasound head becomes the anode (+). The catode (-) is connected thru **black bannana plug**.with minus sing **“-„** on it.

In the case of accesories „**1>>4**“ is connected to the electrotherapy device the ultrasound head becomes the anode (+). The catode (-) is connected thru **red bannana plug**.with minus sing **“+„** on it, independet of selected output A or B.

If you want to apply only electrotherapy with such interconnected devices, it makes no problem. Uncheck the option "**with electro**" on the BTL-4000 Sono device, and the electrotherapy electrodes are automatically connected to the electrotherapy output. Connectors E input and E output are interconnected inside the ultrasound device even if the BTL-4000 Sono device is off.

2.9.3 Interconnection of BTL-4000 Puls, BTL-4000 Sono and BTL vac

If you want to perform combined therapy with these devices, you have to interconnect them mutually – e.g. according to the following picture and table.



(the pictures are only an illustration, for real interconnection follow the below-stated table as well as **Tab. 2.1 Configuration of Output Connectors**)

Electrotherapy BTL-46xx Puls or BTL-56xx Puls		**Ultrasound BTL-4710 Sono or BTL-5710 Sono**	
Connector	**Connected accessories**	**Connector**	**Connected accessories**
E1	interface cable to ultrasound	U1A	ultrasound head 1 cm^2
E2*	interface cable to BTL vac (IN2)	U1B	ultrasound head 4 cm^2
		E input	interface cable to electrotherapy

	* if installed	E output	interface cable to BTL vac (IN1)

2.9.4 Setting and Running of Combined Therapy on Single Devices

After correct interconnection of the devices diagnoses or programs of the combined therapy shall be selected, separately on the electrotherapy and the ultrasound devices. **On the electrotherapy device set the CV mode.** Then it is necessary to attach the respective electrode to the patient to close the electric circuit ultrasound head–patient–electrode (see the schemes above). Now it is possible to run the ultrasound by its **start / stop** button and after achieving the head's contact the ultrasound starts counting time down. Now slowly increase intensity of electrotherapy by turning the **select/intensity** knob to the right (in the "+" direction): the combine therapy is running. If the contact between the ultrasound head and the treated tissue during the therapy was not continuous, the times on both devices may differ, because time countdown on the ultrasound device is not running when contact is interrupted.

2.9.5 End of Combined Therapy on Single Devices

The combined therapy standardly ends after expiration of the set time on both devices. If for any reason you want to end or interrupt therapy before the set time expires, first interrupt therapy on both devices by pressing the **start / stop** buttons.

3 "MENU" BUTTON

After pressing the **menu** button (**11**) you can browse through the following menus using the **select/intensity** knob:

- menu
- user settings

3.1 MENU

After selection of menu and pressing **enter** the following menu appears**:**

- accessories
- encyclopaedia – see Chapter **2.7 Encyclopaedia**
- unit settings
- specific settings

3.1.1 Accessories

In this submenu you can:

- select accessories installation
- display information about connected accessories
- display information about number of patients and arrangement of connectors on the rear side of the device

3.1.1.1 Accessories Installation

Every connectible accessory contains a memory which stores identification data of the accessory. Each connected accessory has the memory that includes identification data of this accessory. On the basis of these data the device recognizes which accessory is connected and if it is compatible and decides how it will work with the accessory. The memory also contains the unique serial number of the accessory.
Since the accessory memory contains quite a lot of information and their upload lasts approximately from 30 second to 2 minutes, accessories installation is intended fore quickening of the work with the device. When installation is performed, only the serial number is read from the accessory during normal operation and the rest of the information is read from the memory of the device.
During the installation process follow the instructions on the screen, in particular the following:

- leave the therapies on all generators off during installation
- do not leave other accessories connected than the one that is being installed. Make sure the installed accessory is connected directly, not via interface cable and the BTL vac or BTL-4000 Sono devices.

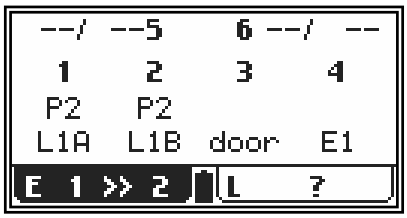
Observing of the above principles is necessary for reduction of electromagnetic interference that could cause improper reading of the memory data.

3.1.1.2 Information on Accessories

In this menu item you can view information about the connected accessories, i.e. its name, serial number, etc., and particularly which generator – output / input – the accessory is designed for.

3.1.1.3 Connectors - Information

This menu item will inform you about the way of connection of the connectors on the rear panel of the device and to how many patients you can connect the device safely.



3.1.2 Unit Settings

This submenu enables to set and display the following parameters:

- access password
- sounds of the device
- auto-power off
- setting of display contrast
- setting of contrast of small (digital) 99 display
- setting of display backlighting
- date and time
- language
- user options
- way of operation
- unit information
- service functions

3.1.2.1 Password Setting

This menu enables to change the password which is required by the device after switch-on. Without entering of this password the device does not allow any further work. The devices are standardly supplied "unlocked", i.e. with password disabled. However, in the devices which have a built-in laser generator, i.e. **BTL-4000 Laser, BTL-48xx L, BTL-48xx xL**, the password cannot be disabled (as required by the respective standard) and its default value is "**0000**".

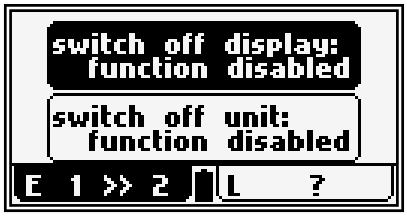
Note:
If you happen to forget the password, you can always use the universal one: "**00000000**"

3.1.2.2 Sound Setting

Sound signalling of pressing of a button etc. and performance of some processes (start of therapy, interruption of therapy, end of therapy, etc.). The factory-set **standard sounds** are sounds of therapy processes. You can set another sound scheme or switch the sounds completely off (**sound scheme 0**).
In the devices with a built-in laser generator, i.e. **BTL-4000 Laser, BTL-48xx L, BTL-48xx xL**, the sound of running therapy cannot be switched off (as required by the respective standard).

3.1.2.3 Auto Switch Off

Here you can set the time after which the display will be switched off, and the idle time after which to switch off the entire device.



3.1.2.4 Setting of Display Contrast

After selection of this menu you can set the optimum contrast (readability) of the display by the **select/intensity** knob (**12**).

Since the display contrast depends on many factors (e.g. temperature of the display), there is also another fast and direct way of setting the contrast. Press simultaneously the **enter** (**13**) and **esc** (**14**) buttons and set the contrast by the **select/intensity** knob (**12**) (when holding the two buttons **enter** and **esc** pressed).

3.1.2.5 Setting Contrast for Small Display

After selection of this menu you can set the optimum contrast (readability) of the lower digital display on the front panel by the **select/intensity** knob (**12**).

3.1.2.6 Setting Backlight

In this item you can select by the **select/intensity** knob (**12**) whether the main display shall be backlighted permanently, shall not be backlighted at all or shall be backlighted only if the device is connected to the mains. This setting has strong influence on the time for which the device can be supplied from the accumulators* without recharging. The switched-on backlighting is considerable load for the accumulators* and reduce the time of operation without recharging.
*) refers only to the devices of the Professional series

3.1.2.7 Date and Time Setting

This item enables to set date and time in the device.

3.1.2.8 Language Setting

Selection of the language of the texts on the display of the device. The defaultly set language is **english**.

3.1.2.9 User Options

In older devices the **enter** and **esc** buttons were arranged the other way round; in this item you can select the new arrangement (**enter** on the right, **esc** on the left) or the old arrangement (**enter** on the left, **esc** on the right).

3.1.2.10 Style of Operation

Here you can select whether the set time and intensity values on the display after the end of therapy shall be zero or equal to the values of the last performed therapy.

3.1.2.11 Configuration - Information

This item displays some important information about the device, such as serial number, firmware version, etc. It is important especially at communication with the service department.

3.1.2.12 Service Functions

3.1.2.12.1 Repair of Files

This function checks the file system in the device – the system of stored information – and fixes possible errors, i.e. for example deletes the files which no link refers to anymore, etc. This function is recommended for use in case of lack of memory when the device rejects to save data, or if you think that some user data have been lost, etc.

3.1.2.12.2 File System Formatting

If the **repair of files** function did not help, use this one. Unfortunately, formatting is accompanied with loss of all user data and user settings of the device.

3.1.2.12.3 Delete Accessories

This function deletes all installed accessories – use it if an accessory is installed improperly – e.g. a bad "scattered" picture on the tab, the connected accessory is not detected (the **question mark** is displayed constantly), etc.

3.1.2.12.4 Default Setting

This function restores all functions of the device as set in the factory. User data – patients, therapies etc. remain preserved.

3.1.2.12.5 Restart of All Geners

This function switches all generators in the device off and on, to get them into the initial status such as at starting of the device. Therapy possibly running on a generator (tab) is stopped. This function should be used only in cases when e.g. by electromagnetic interference a generator switches off and its activity cannot be restored without switching the whole device on and off. This function enables to initialize generators without the need of restarting the whole unit.

3.1.2.12.6 Information about Free Space on Disks

This item displays the current free space in the memory that can be used for user data.. User data are for example patients, saved user diagnoses, I/t curves, etc..
The user can use memory marked "E:"; memory marked "S:" is intended for internal use.

3.1.3 Specific Settings

These settings are different for each generator type, for details see the **User's Guide.**

3.2 USER SETTINGS

After selection of **menu / user settings** there appears a menu with items referring to data saved by the user or to some "extra" features of the selected generator:

- user sequence
- user diagnoses / programs
- recent therapies
- motor point detection*
- accommodation coefficient*
- I/t curve*

*only in the electro-generator and only if the device is equipped with electrodiagnostics – for details see the **User's Guide for Electrotherapy**

3.2.1 User Sequences

This item enables to work with the list of sequences of programs created by the user. The selected sequence can be run, edited and deleted in this menu. A new sequence can be created in the therapy parameters screen in the manual settings.

3.2.1.1 Creating New Sequence

Limitation of choice of currents in one sequence when there is set no pause between sections:

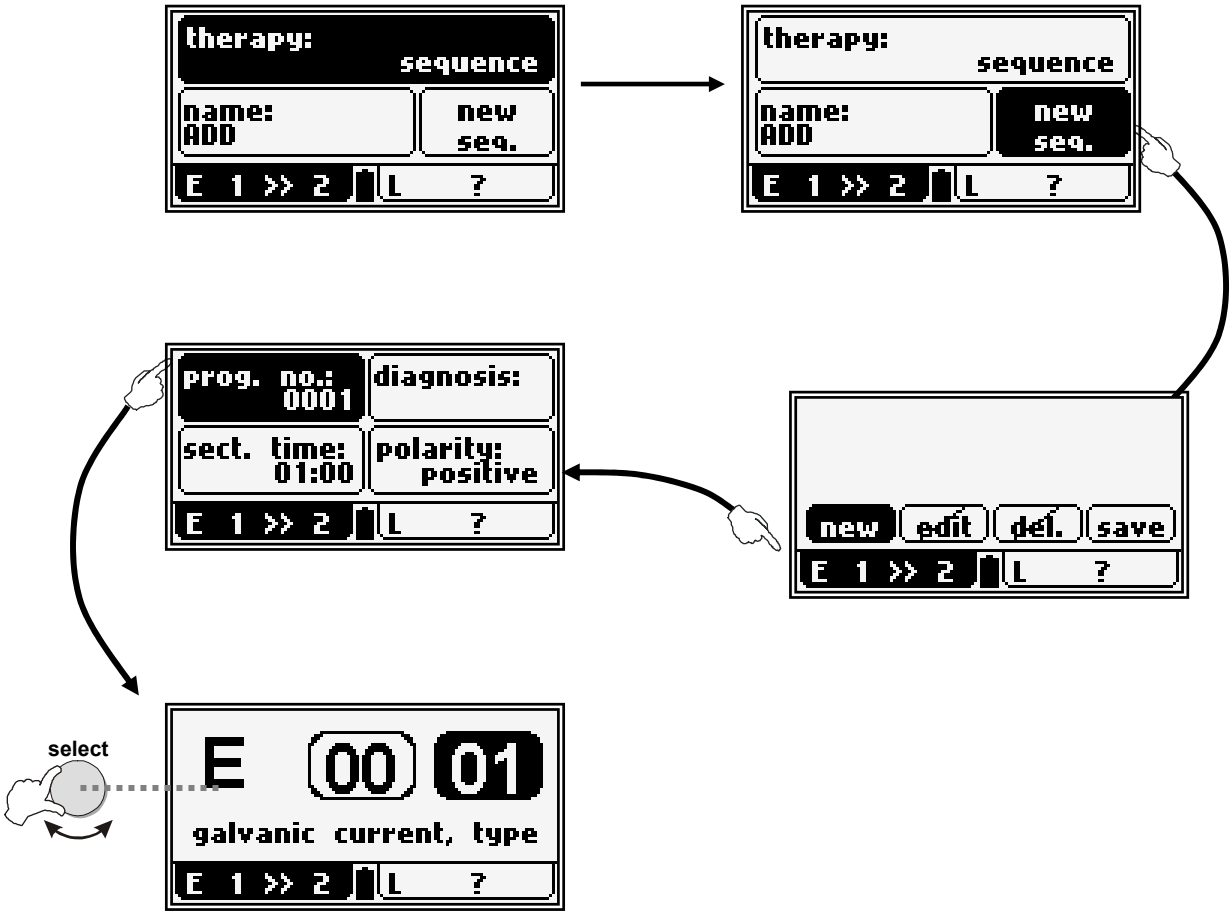
If the "**pause** " option is set (meaning "pause between sections"**),** the unit stops generation after each current and the intensity of the next current has to be set manually. In this case the currents can be sequenced without a limitation and the user can select and combine any current in one sequence. We suggest to set this option for electrotherapy sequences.
If the pause between sections is not set, the device continues generating all currents with the same intensity. Be careful when setting the sequences. Each current is perceived differently by the patient. Whereas in case of TENS the patient tolerates intensity of about 100 mA, the maximum tolerated intensity in case of diadynamic currents may be 10 times lower. Combine in one sequence only currents that are perceived by the patient in a similar way – such as currents with the same pulse length and the maximum difference in frequency 1:10. Monophasic, symmetric and alternating currents should not be mutually combined.

In the mode without pause between sections we therefore recommend creation of sequences containing only the following combinations:

- diadynamic currents

- monophasic pulses of the same length with the DC component (differing in frequency or modulation)
- symmetric pulses of the same length with zero DC component (differing in frequency or modulation)
- alternating pulses of the same length with zero DC component (differing in frequency or modulation)
- mid-frequency bipolar currents (differing in frequency or modulation)
- interference
- TENS (differing in frequency or modulation)
- ultrasound therapies
- laser therapies

In the therapy parameters screen in the manual mode it is possible to select **sequence**, **ultrasound sequence** or **laser sequence** in the **therapy** parameter. Creation of a new sequence is displayed in the following picture.



Repeat the process to insert additional program (section) in the sequence

3.2.1.2 Parameters of Sections in Sequence

Since sequence is a series of individual current programs one after another, it is obvious that parameters of individual sections must be set when creating the programs.
Each program includes several basic therapy parameters such as frequency, pulse length, modulation etc. Set all these data in the manual setting screen and save the set therapy parameters as a user program (diagnosis). Then include this user program in the sequence. When inserting a section in the sequence set the time of the section (except for laser where the time of section depends on the currently connected laser probe). The programs predefined by the manufacturer can be naturally also included in the sequences. In the sequence only polarity can be set for the section (refers to electrotherapy sequence). The other parameters must be specified and saved in the included program.

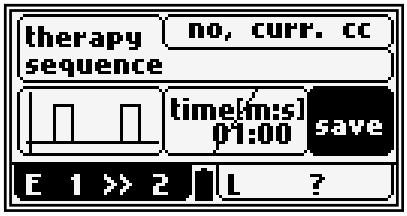
Example: you want to create a sequence of diadynamic DF current (without base, positive polarity, CC mode, time of stimulation: 1 minute) and CP-ISO current (base 10 %, reversal of polarity in the middle of the set time, CC mode, 10 minutes). Press **man** to select the manual mode, set diadynamic currents, DF type, without base, positive polarity, CC mode. Save this setting as a program (for example) E-8001. Then set parameters of the CP-ISO current: base 10 %, positive, reversal, CC mode, and save it as (for example) program E-8002. Then select therapy: **sequence**, press **new seq.**, press **new**, set the program number **8001**, set the time of section **1:00, set positive polarity** and press **esc** or **enter**. Then add the second section in the same way – **new**, program number **8002**, time of section **10:00**, **positive polarity with reversal, esc** or **enter**. Using the **tab** button select the **save** button and press **enter** to save the sequence (for example as the number 9501). The cv/cc mode is set globally for the whole sequence before starting it.

3.2.1.3 Saving New Sequence

The sequence created as described in point **3.2.1.1** can be saved in the following ways.

Either directly from the screen for setting of new sections.

Or from the main manual screen in the same way as the new diagnosis.



User sequences are saved under numbers **9500** - **9999**. They can be found under these numbers in the list of programs, under their names in the list of diagnoses and in the list of sequences.

3.2.2 User Diagnoses/Programs

This item enable to run user therapies, edit their parameters, names and descriptions, delete and sort them using the buttons on the screen and menus after pressing. The work with the user diagnoses / programs is similar to creation of new diagnosis / program – see Chapter **2.8 Therapy Saving**. On each generator tab you can see only the therapies which were created on and belong to the tab.
The icon next to the therapy indicates which generator the therapy belongs to.

3.2.3 Recent Therapies

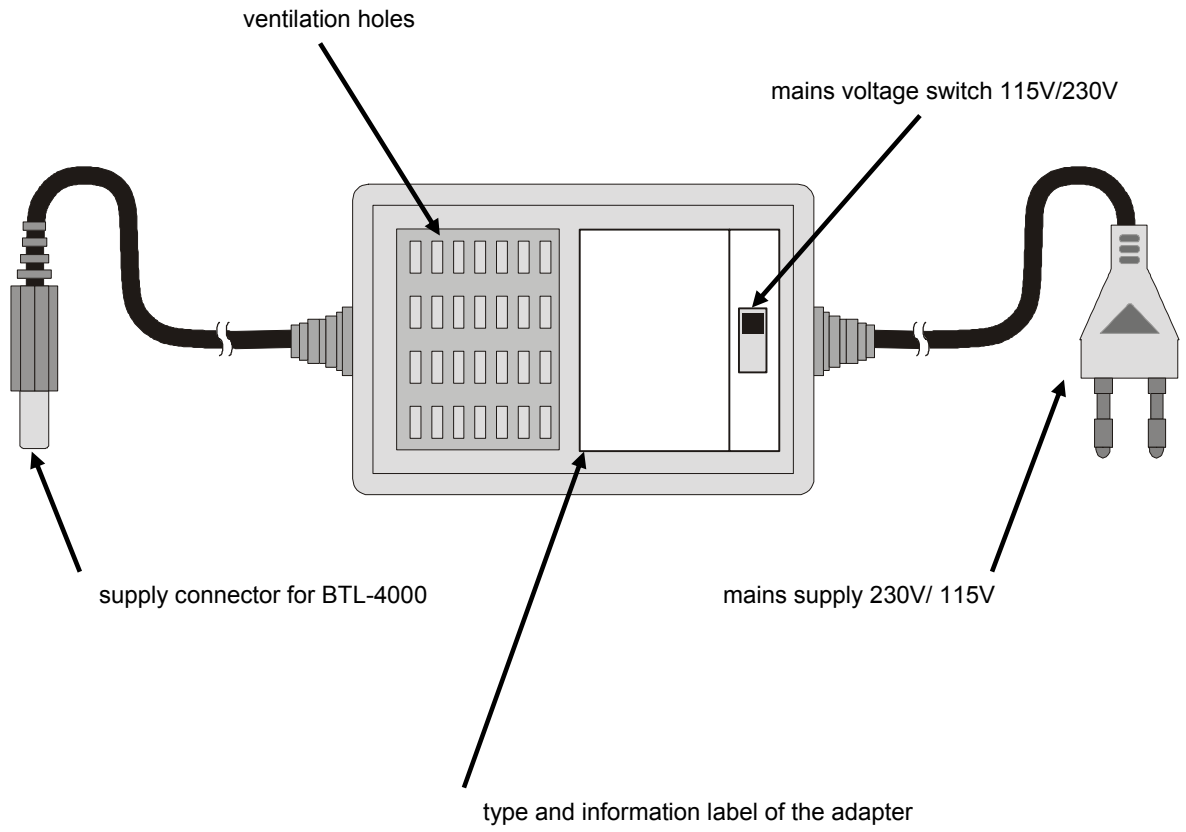
In this item you can select one of the recently performed therapies on the selected tab and after pressing the **load** button start it again or view its parameters.

4 ACCESSORIES

The equipment is not designed for use in connection with other medical devices than those stated in this Manual.
In the following chapters these lists contain all accessories which can be supplied together with the devices.
For detailed information about individual accessories see the enclosed leaflets and/or the respective User's Guide.

4.1 POWER SUPPLY ADAPTER BTL-228

The devices of the BTL-4000 series can be connected to the mains exclusively via the supplied power supply adapter BTL-228. It is forbidden to connect another adapter than BTL-228 to the device.


ventilation holes
mains voltage switch 115V/230V
supply connector for BTL-4000
mains supply 230V/ 115V
type and information label of the adapter

Switching the adapter to other mains voltage
The mains voltage switch is located on the top cover of the adapter. Before switching it is necessary to unplug the mains supply from the socket and disconnect the supply connector from the BTL-4000 device. Turn the switch by a fitting screwdriver or coin so that the lettering next to the switch, to which the slider of the switch is closer, corresponds to the local mains voltage.
This action may only be done by a person acquainted with this procedure! In case of questions contact the authorized BTL service department. The manufacturer takes no responsibility for damages caused by incorrect switching.

Replacement of fuse
The adapter contains secondary tube fuse. The types of the fuse are specified on the label of the adapter. To replace the fuses follow the instructions below.
Before replacement of the fuse make sure that the power supply of the adapter is disconnected from the mains. Unplug the power supply connector from the BTL-4000 device. Turn the segment of the fuse box to the left by a fitting screwdriver or coin and take the fuse out. Insert new fuse(s) and turn the box to the right. **It is forbidden to insert a fuse with other indication than stated near the fuse box.**
This action may only be done by a person acquainted with this procedure!

4.2 ACCUMULATOR

Devices of the Professional series have a built-in accumulator. Its type is specified in Chapter **6 Technical Parameters**. Replacement of the accumulator is provided by the authorized service of BTL devices.

During operation the accumulator is continuously being recharged from the mains. Its recharging and keeping charged is running even if the equipment is switched off and connected to mains and the **mains switch (18)** on the rear panel is in position **I**. At switching off, the device checks the status of the accumulators and if it finds them low, it switches to the charging mode; in the charging mode the display is dark and the main display shows the symbol of recharging battery. After recharging of the accumulator the device automatically switches off completely. Note that the charging process runs only if the device is plugged in the mains and the rocker **mains switch (18)** on the rear panel is in position **I**.

Determination of the accumulator status may take some time, therefore the device may respond with a delay after switching off and then on again.

If the device is supplied from the mains, this status is signalled by the plug picture.

For full charging of the accumulator let it recharge for approximately 6 hours – preferably overnight. The charged accumulator is signalled by the "full battery" picture.

Low accumulator is signalled in two levels of signalling.

- the accumulator is low, but it is still possible to work with the device for a short time, therapy cannot be started, the running therapy will be finished – the battery picture on the display is blinking

- the accumulator is dead, the device switches off automatically

Recharging of the accumulator is signalled by the picture of recharging battery on the display.

To ensure long lifetime of the accumulator we recommend keeping it permanently charged. When it is possible, connect the device to the mains via the adapter and switch the **mains switch (18)** to position **I**. The indication of recharging is displayed, after recharging it goes out and the accumulator will be automatically kept charged.

If the device is left unplugged from the mains for a longer time (even in the OFF status), the accumulators gradually spontaneously discharge. This effect is characteristic of the accumulators and cannot be removed; therefore, if the device has been off and unplugged for a longer time than approximately 2-3 months, we recommend recharging it, preferably for 48 hours without interruption.
For the same reason we recommend charging the device continuously for at least 48 hours immediately after purchase, regardless of the accumulator status indication (you can work with the device normally, only do not unplug it from the adapter, the accumulator recharges even during standard operation of the device). Thus the accumulator gets so –called formatted and will keep working longer without recharging.

4.3 LITHIUM BATTERY

The device contains a lithium battery for backupping of date and time. The type of the battery is stated in Chapter **6 Technical Parameters**. Its possible replacement is provided by the authorized service of BTL devices..

4.4 COMMON ACCESSORIES

external power supply adapter BTL-228 including the mains cable
User's Guide
markers for identification of cables - outputs
cart

4.5 ACCESSORIES FOR ELECTROTHERAPY

User's Guide for electrotherapy
patient cable BTL-236-1
patient cable BTL-236-2
patient cables for BTL-4000 Series Opti, type BTL 226
rubber electrodes 4 x 5 cm^2
rubber electrodes 5 x 7 cm^2
rubber electrodes 5 x 12 cm^2
sponge covers for electrodes 4 x 5 cm^2
sponge covers for electrodes 5 x 7 cm^2
sponge covers for electrodes 5 x 12 cm^2
set of fixation belts
point electrode P5600.013
    point electrode attachment – diameter 2 mm P5600.014
    point electrode attachment – diameter 6 mm P5600.015
    HVT attachment – P5600.017
self-adhesive electrodes
vaginal electrode P5600.010
rectal electrode P5600.011
interface cable between BTL-5000/4000 Series and BTL vac, type PVAC.056
interconnection cable between BTL-4000 Series Opti and BTL vac, type PVAC.056

4.6 ACCESSORIES FOR ULTRASOUND THERAPY

User's Guide for ultrasound therapy
ultrasound head BTL-237, area 1 cm^2
ultrasound head BTL-237, area 4 cm^2
ultrasound gel 235 ml, 5 l, 10 l
interface cable between BTL-56xx Puls, BTL-57xx Sono, type PVAC.056
interface cable between BTL-46xx Puls a BTL-47xx Sono, type PVAC.056

4.7 ACCESSORIES FOR LASER THERAPY

User's Guide for laser therapy
red laser probes BTL-448
infrared laser probes BTL-448
optical attachments for laser probes
warning label "Laser Workplace"
protective goggles OPTE BS 2, L3, 630 – 1350 nm

5 EQUIPMENT MAINTENANCE AND SAFETY

The service inspection including measuring of all parameters of the device and possible recalibration must be performed in intervals shorter than 30 months. The inspection is performed by the BTL service department on the basis of the user's order. If the inspection is not done in the stated term the manufacturer does not guarantee the technical parameters and safe operation of the product.

Keep the device clean, do not store or use it for a long time in enormously dusty environment and do not sink it in any liquid. Before each use check if the equipment and its accessories (especially cables) are not mechanically or otherwise damaged. Do not use the equipment if it is damaged!

The measuring system of the laser device does not require (and does not even enable) any user settings or adjustment. Its inspection is performed at regular recalibration of the device by the authorized service of BTL devices.

Backward measuring of the laser output power does not require (and does not even enable) any user settings or adjustment. Calibration is performed at regular recalibration of the device by the authorized service of BTL devices.

Cleaning of the equipment's surface and of its parts:
For cleaning of the equipment and its parts use only a soft cloth slightly moistened by water or by 2 % solution of detergent. Do not use agents containing alcohol, ammonia, benzine, thinners, etc.
For cleaning of the equipment do not use abrasive materials, otherwise the surface of its parts could be damaged (e.g. the metal part of the ultrasound head).

No part of the equipment needs to be aseptic or sterilized.

Cleaning of accessories which come into contact with the patient (e.g. electrodes, ultrasound heads, laser probes and attachments):
We recommend cleaning of these parts after treating of each patient. For cleaning use agents approved by the competent health officer, e.g. Sekusept, Bacilol etc., for cables of accessories use e.g. Incidur spray etc.
After each application of the divergent probe wipe the head of the probe by a cotton cloth to keep the lens clean. Convergent probes: unscrew the head, wipe the lens and blow the head through by compressed air.

Cleaning of accessories which come into contact with the patient – laser optical attachments:
The optical waveguides (attachments) can be sterilized for 10 minutes at the temperature of 120°C.

Replacement of fuse
The protective fuse is located inside the BTL-4000 device. The type of the fuse is specified in Chapter **6 Technical Parameters** The user may not be replace the fuse; for replacement of the fuse always contact the authorized service of BTL devices.

Transport and Storage
We recommend keeping the packing of the equipment. For transport it is suitable to pack the equipment in this packing which ensures its maximum protection. Unplug the power supply adapter and the cables of accessories. Avoid big shocks. The equipment shall be stored / transported only under conditions defined in Chapter **6 Technical Parameters**

5.1 SAFETY

ATTENTION!

The consumed current or voltage at the connectors marked by the above label can exceed the secure values.
The device is equipped with a system of protection against connection of other accessories than supplied from the manufacturer, so, it cannot work with accessories produced by other manufacturers.

The protection of the equipment is BF-type floating applied part (only if original accessories including power supply adapter BTL-228 are used).

The equipment does not use any medicaments which would be its integral part or would be applied by means of it.

Safety Precautions - General:

- Before first switch-on of the equipment read carefully the User's Manual.
- All staff to use the equipment must be instructed of the way of operation, maintenance and checking of the equipment and of the safety principles.
- The electrical cabling which the equipment will be connected to must be installed and tested according to the existing valid standards (IEC 364). If you are not sure that the mains are completely OK get them inspected by an inspection engineer.
- Check if the parameters of the mains correspond to the requirements of the equipment according to Chapter **6 Technical Parameters**. It must not be used in the environment which implies the danger of explosion or penetration of water into the equipment. It must not be used in connection with flammable anaesthetics or oxidizing gasses (O_2, N_2O, etc.).
- Do not place the equipment within the reach of direct sunshine and strong electromagnetic fields so as to prevent undesirable mutual influence. In case that this undesirable influence occurs put the equipment more distant from the source of interference or contact the authorized service of BTL devices.
- Inspect the equipment thoroughly before each use (loose cables, broken insulation of cables, functions of displays and controls, etc.); in case of any inconsistency stop using the equipment and contact the authorized BTL service department. If the equipment's behaviour differs from the function described in this Manual stop using the equipment and contact the BTL service department.
- If the equipment shows any defect or if you have doubts about its correct function, terminate therapy immediately. If you do not determine the source of uncertainty after thorough study of the Manual, contact the BTL service department. If the equipment is used out of accord with this Manual or is used even if it shows functional differences from this Manual, the user is responsible for the damages caused by the equipment.
- Do not dismantle the equipment in any case, removal of protective covers implies the danger of electrical injury. Possible replacement of the lithium battery, fuses or accumulators may only be done by the authorized BTL service department.
- All material and parts which come into direct contact with the patient's body (as well as for example agents for cleaning of electrodes) must comply with the respective standards related to irritability, allergization, toxicity, genotoxicity, carcinogeneity (ISO 10993-1, ISO 10993-3, ISO 10993-5). The user is responsible for all these materials and parts if not supplied by the BTL equipment supplier.
- The connectors for accessories as well as the other connectors must not be used for connection of anything else than they are designed for, otherwise there is a danger of electrical injury and serious damage to the equipment.
- The equipment does not use or produce any toxic substances during its operation, storage or transport under the stated conditions.
- After bringing the equipment from cold environment to the warmth do not plug it in the mains until the temperatures become equal (i.e. for at least 1 hour).
- Before start of therapy check if all set parameters correspond to your intents.
- Do not apply therapy on damaged skin!
- To terminate the application do not switch off the mains switch but press the **start / stop** knob (**18**). The time interval between switching the mains switch on and off must be at least 3 seconds.
- If after many years of operation it is necessary to discard the equipment, it can be done in a way which is usual for this type of devices after removal of the lithium battery and the leaden accumulator (for the Professional variant). The removed batteries shall be disposed of in the way designated for hazardous waste - not within the

municipal waste. The equipment does not contain any toxic materials which could harm the environment in case of normal way of liquidation.

- The equipment and the accessories must not be used in a way out of accord with this User's Manual.
- During work with this device use the recommended protective equipment.
- Keep the equipment out of reach of children.
- The equipment does not contain any components which could be repaired by the user. Do not remove any covers from the equipment. All repairs should be done by the authorized BTL service department.
- Don't connect equipment to patient when equipment is still connected to computer (via service connector)

Safety Precautions – Electrotherapy:

- When applying DC currents (the **polarity** button is enabled) it is necessary to pay attention to the set intensity and time of application of currents. Wrong values can cause burning of the patient's skin.
- The maximum secure effective value of current density on the electrodes is 2 mA/cm^2 (according to IEC 601-2-10) and can be extended only when electrodes smaller than 70 cm^2 are used. In such case it is necessary to pay higher attention to application of currents! Wrong values can cause burning of the patient's skin.
- Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
- For contraindications see Chapter **5.2 Contraindications**. Use of electrotherapy in the cases of contraindication must be approved by a specialist.
- Simultaneous connection of the patient to a high-frequency surgical device may cause burning in the place of the electrodes and possible damage to the electrotherapy device.
- Simultaneous connection of the patient to an ECG monitor or an ECG alarm system may cause temporary malfunction of the ECG systems or unreliability of the values measured by the ECG systems.
- Operation of the equipment close to (within 1 m) a short-wave or micro-wave therapeutic device may cause instability of the equipment's output.
- All supplied electrodes can be used for maximum intensity of currents and voltage that can be set on the device.

Safety Precautions – Ultrasound:

- Protect the heads consistently from shocks and frost. Do not uselessly bend the mains cable.
- **During therapy hold the head so that you do not touch its metallic parts.**
- An impact on the metal part of the head as well as an intense impact on the head's case may negatively change the parameters of the therapeutic head.
- For contraindications see Chapter **5.2 Contraindications**. Use of ultrasound therapy in the cases of contraindication must be approved by a specialist.
- For therapy use only the BTL ultrasound gel; the head is not tested for other gels or oils and their use could damage the head. If you still want to use other gels, we recommend them to be only water-based gels. Never use paraffin-based gels.

Safety Precautions – Laser:

- Mark the laser workplace by respective warning notices and connect the door switch.
- Equip the laser workplace with an operating code which must be approved by the competent health officer.
- When using a laser probe with an output of 200 mW or more (300 mW, 400 mW) and if the laser power is set higher than 150 mW, the duration of therapy must not exceed 15 min.
- Attention – use of any other than the stated control and setting elements and processes may cause dangerous exposition to radiation.
- The equipment works with laser beam of the 3B class . When working with the beam follow all instructions stated in this Manual and in the laser therapy User's Guide. Prevent the laser beam from hitting eyes, thyroid and other endocrine glands, head, etc. (see the User's Guide). Both the therapist and the patient have to wear the supplied protective goggles during therapy. Incorrect handling of the equipment (out of accord with this Manual) may cause danger radiation and even damage to eyes! In such a case the user is responsible for all damages.
- During radiation do not disconnect the probe from the equipment and do not switch the equipment off.
- **Protect the laser probe consistently from impacts !!!! The probe is not waterproof!**
- **Protect yourself and your neighbourhood from being directly hit by the laser beam.**
- For contraindications see Chapter **5.2 Contraindications**. Use of laser therapy in the cases of contraindication must be approved by a specialist

5.2 CONTRAINDICATIONS

The list of contraindications gives the cases when the manufacturer does not recommend to apply the selected therapy. A specialised medical workplace, realizing possible consequences, may decide to apply the therapy in spite of it. However, in such case they bear all the responsibility for this action.

5.2.1 Contraindications for Electrotherapy

- active tuberculosis
- allergy to solutions used for dampening of the electrode cover sponges
- application in the areas of heart and eyes
- groundless stimulation - "placebo effect"
- pacemaker
- cardiovascular diseases
- cochlear implants
- metal implants and malignancies in the current path
- skin defects and skin inflammations
- bleeding conditions
- menstruation
- tumorous diseases
- sensitivity disorders (relative KI) in the area of electrode placement
- psychopathological syndromes and organic psychosyndromes
- multiple sclerosis
- pregnancy
- inflammation of veins and lymphatic paths

5.2.2 Contraindications for Ultrasound Therapy

- active tuberculosis
- allergy to the applied ultrasound gels
- application on peripheral nerves (located on the bone, close to the skin surface)
- application on endocrine glands
- application on areas around eyes, brain, spinal cord and heart
- emphysema, bronchiectasia
- epiphyses of growing bones
- gonads
- pacemaker
- cardiovascular diseases
- cochlear implants
- osseous protrusions just under the skin
- metal implants
- skin defects and skin inflammations
- blood diseases
- bleeding conditions
- menstruation
- tumorous diseases
- blood circulation deficiency
- conditions after laminectomy
- pregnancy

5.2.3 Contraindications for Laser Therapy

- application in the area of eyes – possibility of direct eye irradiation and damage to retina
- menstruation
- tumorous diseases
- Irradiation of malignancies and potentially precancerous growths
- Irradiation of patients with cochlear implants
- Irradiation of endocrine glands
- worn out patients, patients with febrile conditions

- pulse modes (whether red or infrared beams) must not be used for patients with anamnesis of seizure (epilepsy)
- pregnancy

5.3 USEFUL ADDRESSES

The product is manufactured in accordance with the EU Medical Devices Directive by :

BTL Industries Ltd.
Suite 401 Albany House
324-326 Regents Street
London, W1B 3BL United Kingdom
E-mail: sales@btlnet.com
http://www.btlnet.com

For service, please contact service department at service@btlnet.com.

5.4 WARRANTY

The Manufacturer of this product warrants the product to be free from defects in workmanship and material for a period of twelve months after the date of shipment from the factory. This warranty excludes any disposable items and accessories, including, but not limited to cables or leads, power cords and electrodes. The manufacturer agrees to correct such defects without charge, or at its option to replace the item with a comparable model. To register and be eligible for warranty service, you must send or fax the fully completed warranty registration form within 30 days of installation. All costs of shipment are the responsibility of the purchaser. Damage to any part such as by accident or misuse or improper installation or by use of any accessories or abrasive material not produced by the Manufacturer is not covered by this warranty. Because of varying climatic conditions, this warranty does not cover any changes in finish, including rusting, pitting, corrosion, tarnishing or peeling. Servicing performed by unauthorized persons render this warranty invalid. There is no other express warranty. The Manufacturer hereby disclaims any and all warranties, including but not limited to, those of merchantability and fitness for a particular purpose to the extent permitted by law. The duration of any implied warranty which cannot be disclaimed is limited to the time period as specified in the express warranty. The Manufacturer shall not be liable for incidental, consequential, or special damages arising out of, or in connection with product use or performance except as may be otherwise accorded by law.

This warranty may differ from the warranty terms and conditions provided by your supplier and by applicable laws in your country.

6 TECHNICAL PARAMETERS

6.1 TECHNICAL PARAMETERS OF THE BTL-4000 SERIES DEVICES

Device Type:	BTL-4000 Series Optimal	BTL-4000 Series Professional
Display:	graphic	
dimensions (mm):	70x38	
resolution:	128 x 64	
Low battery indication:	on the display	
Weight including the adapter (max.):	2.5 kg	3.1 kg
Dimensions (l x w x h) (mm):	350x160x145	
Operating conditions:		
temperature:	+ 10 °C to + 40 °C	
relative humidity:	30 % to 75 %	
atmospheric pressure	700 hPa to 1060 hPa	
position	horizontal – on legs	
type of operation	continuous	
Transport and storage conditions:		
temperature:	- 10 °C to + 55 °C	
relative humidity:	25 % to 85 %	
atmospheric pressure	650 hPa to 1100 hPa	
position	any	
time of storage:	max. 1 year	
additional conditions:	transport only in the supplied packing recharge the accumulators at least 2x a year	
Power supply:	supply only via the external supply adapter BTL-228	
input:	60 W	
input voltage	~ 18 V to 25 V, alternating	
frequency:	50 Hz to 60 Hz	
protection class:	II (according to IEC 536, ČSN 33 0600)	
internal fuse:	T5A / 250V, safety fuse on the printed circuit, acc. to IEC 127-2 (replacement may only be done by the authorized service)	
mains switch:	on the rear panel of the device, positions **0** and **I**	
power switch	on the front panel of the device, marked **on/off**	
covering:	IP20	
Internal chemical sources:		
battery:	lithium battery CR2032	
lead accumulator:	no	2x 6 V / 1.2 Ah, maintenance-free 1-2 hours of common use;
capacity of the accumulator:	no	strongly depends on the energy intensiveness of the applied therapies
charger:	no	internal, time needed for 100 % charging is approx. 6 hours
Classification		
applied parts type	BF	
class according to MDD 93/42/EEC	IIb	
Therapy duration		
for electro and laser therapies	0 to 100 minutes	
for ultrasound therapies	0 to 30 minutes	
step of setting	1 second	
accuracy of therapy time	± 2 % of the set value	
Accuracy of time values	5 seconds per day	

6.2 TECHNICAL PARAMETERS OF POWER SUPPLY ADAPTER BTL-228

Device Type:	BTL-228
Operating conditions:	
temperature:	+ 10 °C to + 40 °C
relative humidity:	30 % to 75 %
atmospheric pressure	700 hPa to 1060 hPa
position	horizontal
type of operation	continuous, use indoor only
Transport and storage conditions:	
temperature:	- 10 °C to + 55 °C
relative humidity:	25 % to 85 %
atmospheric pressure	650 hPa to 1100 hPa
position	any
time of storage:	max. 5 years
Power supply of the device:	
maximum input:	70 W
input mains voltage	99V to 126V (115 V nominal), alternating 198V to 252V (230 V nominal), alternating
frequency:	50 Hz to 60 Hz
protection class:	II (according to IEC 536, ČSN 33 0600)
fuse:	T4A / 250V, tube fuse 5x20mm, according to IEC 127-2 (replacement possible by user)
covering:	IP20
type of connector of the device	mini 2 poles
Output parameters	
output voltage	18VAC
output current	3.6A
frequency:	50 Hz to 60 Hz
Insulation barriers	
mains – output (output connector)	4kV

6.3 BASIC PARAMETERS OF ELECTROTHERAPY GENERATOR

Adjustable values

Output current*	max. 140 mA (maximum instantaneous value)
Output current - HVT*	max. 4 A (maximum instantaneous value)
Output current - microcurrents	max. 999 μA (maximum instantaneous value)
Output voltage	max. 130 V (maximum instantaneous value)
Output voltage - HVT	max. 390 V (maximum instantaneous value)
*maximum value for some currents is limited according to IEC 601-2-10	
Tolerance of output amplitude	± 10 % for 5 mA (5 V, 5 μA) and higher; otherwise ± 30 % ± 10 % for 35 V and higher; otherwise ± 30 % (for HVT)
Tolerance of time parameters of current	standard ± 5 %; maximum ± 15 % standard ± 20 % for modulation of HVT from 5 s; otherwise ± 30 %
Nominal load impedance	500 Ω
Internal output resistance in CV mode	96 Ω ± 10 %
Internal output resistance in CC mode	47 kΩ ± 10 %
Output capacity	standard 150 pF
Output polarity – can be selected	positive / negative / with reversal in the middle of the therapy
Positive polarity	red banana plug = + = anode; black banana plug = - = cathode
Negative polarity	red banana plug = - = cathode; black banana plug = + = anode

6.4 BASIC PARAMETERS OF ULTRASOUND GENERATOR

Adjustable values

Effective intensity	
Continuous operation	0.1 to 2 W/cm^2 ± 20 % for output intensity higher than 0.2W/cm^2
Pulse operation	0.1 to 3 W/cm^2 ± 20 % for output intensity higher than 0.2W/cm^2
Working frequency - Optimal	1 MHz ± 5%
Working frequency - Professional	1 MHz ± 5% and 3.2 MHz ± 5%
Modulation frequency	10 to 150 Hz ± 5%
Duty factor	6 to 100% ± 5% of the set value
Duty factor	6.25% (1:16), 12.5% (1:8), 25% (1:4), 50% (1:2), 100% (1:1) ± 5% of the set value
Maximum output power	12W

Parameters of pulses

Duty factor	Frequency 10 Hz period 100 ms		Frequency 50 Hz period 20 ms		Frequency 100Hz period 10 ms		Frequency 150 Hz period 6.67 ms	
	Pulse length	Pause length	Pulse length	Pause length	Pulse length	Pause length	Pulse length	Pause length
50 %	50 ms	50 ms	10 ms	10 ms	5 ms	5 ms	3.33 ms	3.33 ms
25%	25 ms	75 ms	5 ms	15 ms	2.5 ms	7.5 ms	1.67 ms	5 ms
10%	10 ms	90 ms	2 ms	18 ms	1 ms	9 ms	0.67 ms	6 ms
6%	6 ms	94 ms	1.2 ms	18.8 ms	0.6 ms	9.4 ms	0.40 ms	6.27 ms

Steps of adjustable values

Intensity	0.1 W/cm^2
Modulation frequency	10 Hz

6.5 BASIC PARAMETERS OF LASER GENERATOR

Indication of emission of laser radiation	green pilot light on the probe, supplementary lighting of the probe, sound
Indication of readiness for emission	on the screen
Indication of unreadiness for emission	on the screen
Additional safety means	- warning labels on the device case and on the probe - warning label for the entrance door of the workplace - remote control connector

Remote control connector (door switch)

input voltage	AC / DC 5 V to 35 V (external power supply) / automatic polarity recognition
input current	max. 10mA
active level	settable positive / negative logic

Adjustable values

Frequency* **	0 – 5000 Hz
accuracy of frequency	± 3 % of the set value
Dose*	0.1 – 100.0 J/cm^2
accuracy of dose	±20% (according to IEC 60601-2-22)
Area*	0.1 – 100.0 cm^2
accuracy of area	see BNR
Output*	5.0 – 500 mW (depending on the connected laser probe)
accuracy of output	±20% (according to IEC 60601-2-22)
Duty factor**	10 – 90 %
accuracy of duty factor	±1% of the range of DF

*) The stated values are maximum. The actual values depend on the type of the connected laser generator and on the purchased configuration of the device

**) Can be set only in the pulse mode, in the continuous mode it is always 100%

***) Zero frequency means continuous operation of laser

6.6 TECHNICAL PARAMETERS OF ULTRASOUND HEADS

BTL-237-1-13 – small head

Effective radiation area (ERA)	
ERA (ČSN EN 61689)	0.7 cm^2 ± 20%
ERA (21 CFR 1050)	0.9 cm^2 ± 20%
Maximum effective intensity	3 W/cm^2 ± 20%
Maximum effective acoustic power	2.1 W ± 20%
Radiation frequency	1 MHz and 3.2 MHz ± 5%
Type of beam	collimated
BNR	< 8
Covering grade according to EN 60 529	IP 67

BTL-237-4-13 – large head

Effective radiation area (ERA)	
ERA (EN 61689)	3.2 cm^2 ± 20%
ERA (21 CFR 1050)	4.4 cm^2 ± 20%
Maximum effective intensity	3 W/ cm^2 ± 20%
Maximum effective acoustic power	9.6 W ± 20%
Radiation frequency	1 MHz and 3.2 MHz ± 5%
Type of beam	collimated
BNR	< 8
Covering grade according to EN 60 529	IP 67

6.7 TECHNICAL PARAMETERS OF LASER PROBES

Laser probes with red (visible) radiation:

Type:	**BTL-448-03RD**	**BTL-448-03RC**	**BTL-448-05RD**	**BTL-448-05RC**
Output power:	30 mW ± 20 %	30 mW ± 20 %	50 mW ± 20 %	50 mW ± 20 %
Wavelength:	685 nm	685 nm	685 nm	685 nm
Class*:	3B	3B	3B	3B
Beam:	divergent	collimated	divergent	collimated
Aperture:	Ø 2 mm	Ø 4.4 mm	Ø 2 mm	Ø 4.4 mm
BNR:	0.28 rad ± 0.05 rad	0.015 rad ± 0.005 rad	0.28 rad ± 0.05 rad	0.015 rad ± 0.005 rad
NOHD:**	0.2 m	2.3 m	0.2 m	3.4 m

Laser probes with infrared (invisible) radiation:

Type:	**BTL-448-05IC**	**BTL-448-10IC**	**BTL-448-20IC**	**BTL-448-30IC**
Output power:	50 mW ± 20 %	100 mW ± 20 %	200 mW ± 20 %	300 mW ± 20 %
Wavelength:	830 nm	830 nm	830 nm	830 nm
Class*:	3B	3B	3B	3B
Beam:	collimated	collimated	collimated	collimated
Aperture:	Ø 4.4 mm	Ø 4.4 mm	Ø 4.4 mm	Ø 4.4 mm
BNR:	0.015 rad ± 0.005 rad	0.015 rad ± 0.005 rad	0.015 rad ± 0.005 rad	0.015 rad ± 0.005 rad
NOHD:**	8.5 m	12.1 m	12.5 m	16.6 m

Type:	**BTL-448-40IC**
Output power:	400 mW ± 20 %
Wavelength:	830 nm
Class*:	3B
Beam:	collimated
Aperture:	Ø 4.4 mm
BNR:	0.015 rad ± 0.005 rad
NOHD:**	19.2 m

*Laser class is classified according to IEC 60601-2-22:1995 and IEC 60825-1:1993/A2:2001.
**NOHD – nominal ocular hazard distance (nominal distance from the laser aperture in which the eye damage by laser beam should not happen)

6.8 APPLICABLE STANDARDS

Name	IEC, EN, ISO, MDD
Medical electrical equipment. Part 1: General requirements for safety	IEC 601-1
Amendments to IEC 601-1	A2, A11 a A12
Medical electrical equipment Part 1: General requirements for safety 1.Collateral standard: Safety requirements for medical electrical systems	IEC 60601-1-1
Z Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standard: Electromagnetic compatibility. Requirements and tests	IEC 601-1-2
Industrial, scientific and medical (ISM) radio-frequency equipment - Radio disturbance characteristics - Limits and methods of measurement	EN 55011
Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques - Section 2: Electrostatic discharge immunity test - Basic EMC Publication	IEC 61000-4-2
Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques - Section 3: Radiated, radio frequency, electromagnetic field immunity test	IEC 61000-4-3
Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques - Section 4: Electrical fast transients/burst immunity test - Basic EMC Publication	IEC 61000-4-4
Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques - Section 5: Surge immunity test	IEC 61000-4-5
Medical electrical equipment Part 1: General requirements for safety 4.Collateral standard: Programmable electrical medical systems	IEC 601-1-4
Medical devices – Risk analysis	EN 14971
Biological evaluation of medical devices - Part 1: Evaluation and testing	ISO 10 993-1
The Medical Devices Directive 93/42/EEC	MDD 93/42/EEC
Medical electrical equipment Part 2: Particular requirements for the safety of ultrasonic therapy equipment	IEC 601-2-5
Medical electrical equipment - Part 2: Particular requirements for the safety of nerve and muscle stimulators	IEC 601-2-10
Medical electrical equipment Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment	IEC 601-2-22
Safety of laser products. Part 1: Equipment classification, requirements and user's guide	IEC 60 825-1
Amendments to IEC 60 825-1	A1, A2

6.9 INTERCONNECTION WITH OTHER DEVICES

BTL-4000 Puls can be interconnected with: BTL vac, BTL-4000 Sono, BTL-5000 Sono, BTL-12, BTL-07p
BTL-4000 Combi can be interconnected with: BTL vac, BTL-12

This product is manufactured in accordance with the EU Medical Devices Directive by:

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7 CONFIGURATIONS OF DEVICES

7.1 CONFIGURATIONS OF COMBINED DEVICES BTL-4000 COMBI

Type:	4810S Professional	4810L Professional	4800SL Professional	4810S Optimal	4810L Optimal	4800SL Optimal
mains supply	x	x	x	x	x	x
built-in accumulator	x	x	x			
manual mode	x	x	x	x	x	x
predefined programs	x	x	x	x	x	x
predefined diagnoses	x	x	x	o	o	o
user programs	50	50	50	5	5	5
ultrasound head 1MHz				x		x
ultrasound head 1/3MHz	x		x			
el. patient cables – basic				x	x	
el. p. cab. with visual detection	x	x				
possibility to connect BTL-vac	x	x		x	x	
electrotherapies	1	1		1	1	
ultrasound therapies	1		1	1		1
laser therapies		1	1		1	1
number of simultaneously running therapies	2	2	2	2	2	2
number of simultaneously running electrotherapies.	1	1		1	1	
sound schemes	x	x	x	x	x	x
number of simultaneously treated patients	2	2	2	2	2	2

7.2 CONFIGURATIONS OF ELECTROTHERAPY DEVICES BTL-4000 PULS

Type:	4610 Professional	4615 Professional	4620 Professional	4625 Professional	4640 Professional	4610 Optimal	4620 Optimal	4625 Optimal
mains supply	x	x	x	x	x	x	x	x
built-in accumulator	x	x	x	x	x			
manual mode	x	x	x	x	x	x	x	x
pre-defined programs	x	x	x	x	x	x	x	x
pre-defined diagnoses	x	x	x	x	x	o	o	o
user programs	50	50	50	50	50	5	5	5
ultrasound head 1MHz								
ultrasound head 1/3MHz								
el. patient cables – basic						x	x	x
el. p. cab. with visual detection	x	x	x	x	x			
possibility to connect BTL-vac	x	x	x	x	x	x	x	x
electrotherapy outputs	1	1	2	2	4	1	2	2
ultrasound outputs								
laser outputs								
number of simultaneously running therapies	1	1	2	2	4*	1	2	2
number of simultaneously running electrotherapies.	1	1	2	2	2	1	1	1
sound schemes	x	x	x	x	x	x	x	x
number of simultaneously treated patients	1	1	2	2	2	1	1	1
galvan	x	x	x	x	x	x	x	x
träbert, farad, neofarad	x	x	x	x	x	x	x	x
diadynamics	x	x	x	x	x	x	x	x
TENS	x	x	x	x	x	x	x	x
rectangular pulses	x	x	x	x	x			x
triangular pulses	x	x	x	x	x			x
exponential pulses	x	x	x	x	x			x
combined pulses	x	x	x	x	x			x
intermittent pulses								
stimulation pulses	x	x	x	x	x			x
russian stimulation	x	x	x	x	x	x	x	x
2-pole interference	x	x	x	x	x	x	x	x
4-pole interference			x	x	x		x	x
isoplanar field (interference)				x	x			x
vector field (interference)				x	x			x
HVT	o	o						
h – waves		x		x	x			
spastic currents					x			

micro currents		x		x	x			
leduc current		x		x	x			
mid-frequency waves					x			
pulses with exponential rise	x	x	x	x	x			x
preset sequences		20	20	20	20		5	5
electrodiagnostics					x			

7.3 CONFIGURATIONS OF ULTRASOUND DEVICES BTL-4000 SONO

Type:	4710 Professional	4720 Optimal
mains supply	x	x
built-in accumulator	x	
manual mode	x	x
number of ultrasound therapies	1	1
user programs	50	5
predefined diagnoses	x	o
preset programs	x	x
language versions	x	x
sound schemes	x	x
recent therapies	20	20
Ultrasound parameters:		
head 1 MHz		x
heads 1 and 3 MHz	x	
detection of contact	continuous	continuous
continuous mode of operation	x	x
pulse mode of operation	x	x
duty factor	x	x

7.4 CONFIGURATIONS OF LASER DEVICES BTL-4000 LASER

Type:	4110 Professional	4110 Optimal
mains supply	x	x
built-in accumulator	x	
manual mode	x	x
number of laser therapies	1	1
user programs	50	5
predefined diagnoses	x	o
preset programs	x	x
language versions	x	x
sound schemes	x	x
recent therapies	20	20